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TABLE 3
Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies[1,9-57,59-117] *(continued)*

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Vaginal perforation					
Pubovaginal	1	0.00% (0.00–2.46%)	0	326	0.00–0.00%
Burch	2	0.21% (0.03–1.50%)	1	475	0.00–0.30%
Retropubic	12	0.73% (0.40–1.2%)	19	1892	0.00–15.00%
Minisling	10	1.3% (0.8–1.9%)	20	1538	0.00–4.84%
Obturator	20	2.8% (2.2–3.5%)	82	2498	0.00–10.87%
Deep vein thrombosis					
Obturator	2	0.00% (0.00–12.03%)	0	68	0.00–0.00%
Retropubic	3	0.06% (0.01–0.43%)	1	1660	0.00–0.07%
Pubovaginal	4	0.35% (0.09–1.42%)	2	567	0.00–1.28%
Burch	3	0.58% (0.11–1.4%)	4	506	0.00–3.23%

AE, adverse event; *CI*, confidence interval.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

quality based on the likelihood of biases and completeness of reporting. Grades for different outcomes could vary within the same study.

Data synthesis and analysis

We were able to identify comparisons for MUS vs Burch, pubovaginal slings vs Burch, pubovaginal slings vs MUS, retropubic MUS vs obturator MUS, retropubic MUS vs retropubic MUS (based on route of passage), obturator MUS vs obturator MUS (based on route of passage), and minisling vs other sling. When at least 3 RCTs compared the same surgeries for the same outcomes and provided adequate data for metaanalysis (including for AEs), we performed random effects model metaanalyses to estimate pooled odds ratios (ORs). We included data from the time point closest to 12 months' follow-up that were reported. For objective cure, studies used cough stress test, pad test, or both methods. Across studies, we treated the different methods as equivalent (ie, we included both methods in the metaanalyses), but when a single study reported both methods, we preferentially chose stress test over pad test or a combined outcome (both pad and stress tests). When at least 3 studies (pre-post, nonrandomized comparative, or RCT) reported the same AE for the same sling type, we performed random effects model metaanalyses of the arcsine transformed proportion of women with the outcome.[6] The arcsine transformed proportion was used to minimize bias due to the nonnormal distribution when proportions are close to 0. However, when the total number of events was <3 or metaanalysis gave an implausible summary estimate, the exact proportion and confidence interval (CI) were calculated for the total number of events and women at risk.[7] These absolute rates of AEs are compared qualitatively between procedures, and all data are presented in Table 3.

For each comparison of different sling types (or vs Burch), we generated an evidence profile by grading the quality of evidence for each outcome according to the Grades for Recommendation, Assessment, Development, and Evaluation system. The process considered the methodological quality, consistency of results across studies, directness of the evidence, and imprecision or sparseness of evidence to determine an overall quality of evidence. Four quality rating categories were possible: high (A), moderate (B), low (C), and very low/insufficient (D).[8] Evidence profiles for the reviewed studies are in the Appendix.

We developed clinical practice guideline statements incorporating the balance between benefits and harms of the compared interventions when the data were sufficient to support these statements. Each guideline statement was assigned an overall level of strength of the recommendation (1 = strong, 2 = weak) based on the quality of the supporting evidence and the size of the net benefit. The strength of a recommendation indicates the extent to which one can be confident that adherence to the recommendation will do more good than harm. The wording and its implications for patients, physicians, and policymakers are detailed in Table 4.

We presented our findings at the 39th Annual Scientific Meeting of the Society of Gynecologic Surgeons in April 2013 in Charleston, SC. A link to the guidelines and manuscript was then e-mailed to the entire membership for review and vetting in August 2013 prior to submission for publication.

Results

The MEDLINE search identified 2849 abstracts, of which we retrieved 881

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TABLE 4
Society for Gynecologic Surgeons Systematic Review Group sling surgery for stress urinary incontinence in women, clinical practice guidelines

Midurethral sling vs Burch (open or laparoscopic)

For women considering midurethral slings or Burch procedures for treatment of SUI, we suggest either intervention for objective and subjective cure and that decision be based on: (1) which adverse events are of greatest concern to patient; and (2) any other planned concomitant surgeries (vaginal vs abdominal route). (1A)

- Midurethral slings may result in lower rates of perioperative adverse events such as blood loss, postoperative pain, operating room time, hospital stay, bowel injury, wound infection, and hematomas. (1C)
- Burch procedures may result in lower rates of return to operating room for retention, erosion, overactive bladder symptoms, and groin pain. (1C)

Pubovaginal sling vs Burch

For women considering pubovaginal slings or Burch procedures for treatment of SUI, we recommend pubovaginal slings to maximize cure outcomes. (1A)

- Burch procedure results in lower rates of erosion, overactive bladder symptoms, and retention requiring reoperation. (1C)
- Pubovaginal slings result in lower rates of wound infection, bladder/vaginal perforation, and bowel injury. (1C)

Pubovaginal sling (biologic and synthetic) vs midurethral sling (only TVT was studied)

For women considering pubovaginal or midurethral sling for treatment of SUI, we recommend midurethral sling for better subjective cure outcomes. (2C)

- Midurethral slings may result in lower rates of perioperative outcomes such as operating room time, blood loss, and hospital stay. (2D)
- Pubovaginal slings may result in lower rates of adverse events such as urinary tract infection and vaginal perforation. (2D)

Retropubic vs obturator midurethral slings

For women considering retropubic or transobturator midurethral sling, we recommend either intervention for objective and subjective cure and that decision be based on which adverse events are of greatest concern to patient. (1A)

- Retropubic slings result in lower rates of sling erosion, need to return to operating room for treatment of sling erosion, groin/leg pain, and vaginal perforation. (1D)
- Transobturator midurethral slings result in shorter operative time, fewer bladder/urethral perforations, less perioperative pain, fewer urinary tract infections, and less overactive bladder symptoms. (1D)

Obturator vs obturator or retropubic vs retropubic midurethral slings

There is insufficient evidence to provide recommendation for choosing among specific obturator or retropubic slings.

Minisling (TVT-Secur U/H position and MiniArc studied) vs other sling (TVT and TVT-O studied)

For women considering minislings (specifically TVT-Secur in H or U configuration) compared to traditional midurethral slings for treatment of SUI, we recommend traditional midurethral sling to maximize cure rates. (1A)

- Route of traditional midurethral sling that would be performed is important consideration in regard to adverse events compared with minislings. For example, minislings have similar rates of postoperative overactive bladder symptoms compared with obturator slings, but lower rates compared with retropubic slings. Exposure of sling postoperatively is similar between obturator slings and minislings, but retropubic slings have lower rates than both other types. (1D)
- Dyspareunia is more common with minisling than either retropubic or obturator sling, but absolute rates are low for all types of slings. (1D)

MiniArc; AMS, Minnetonka, MN; TVT-O; Ethicon Gynecare, Cincinnati, OH; TVT-Secur; Ethicon Gynecare.

SUI, stress urinary incontinence; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

full-text papers that were further assessed in detail (Figure 1). This process resulted in 127 papers detailing RCTs (Table 1), from which there were 49 unique, eligible trials. There were also 704 additional papers reflecting other study designs, which were considered for AE data (Table 3). After limiting the non-RCT papers to those with the largest number of patients, we included 39 of those studies in addition to collecting AE information from RCTs (Table 3).

We categorized the trials into 6 comparisons, which are discussed in detail below and in Table 1.

MUS vs Burch urethropexy

There were 10 RCTs for this comparison with overall moderate quality of evidence (Supplementary Table 1).[9-18] Two studies examined obturator MUS,[10,15] while the remaining analyzed a retropubic sling vs Burch urethropexy, which was performed via laparotomy except in 3 studies that analyzed laparoscopic Burch surgery.[11,13,14] There were no studies comparing minislings to Burch urethropexy.

The evidence reviewed did not support a difference between the 2 surgeries with regard to objective cure, subjective cure, quality-of-life, or sexual function outcomes. While 8 studies provided data about cure outcomes, there were fewer studies evaluating quality of life[13,16,18] and sexual function.[18]

Metaanalysis of objective cure did not show a significant difference for sling

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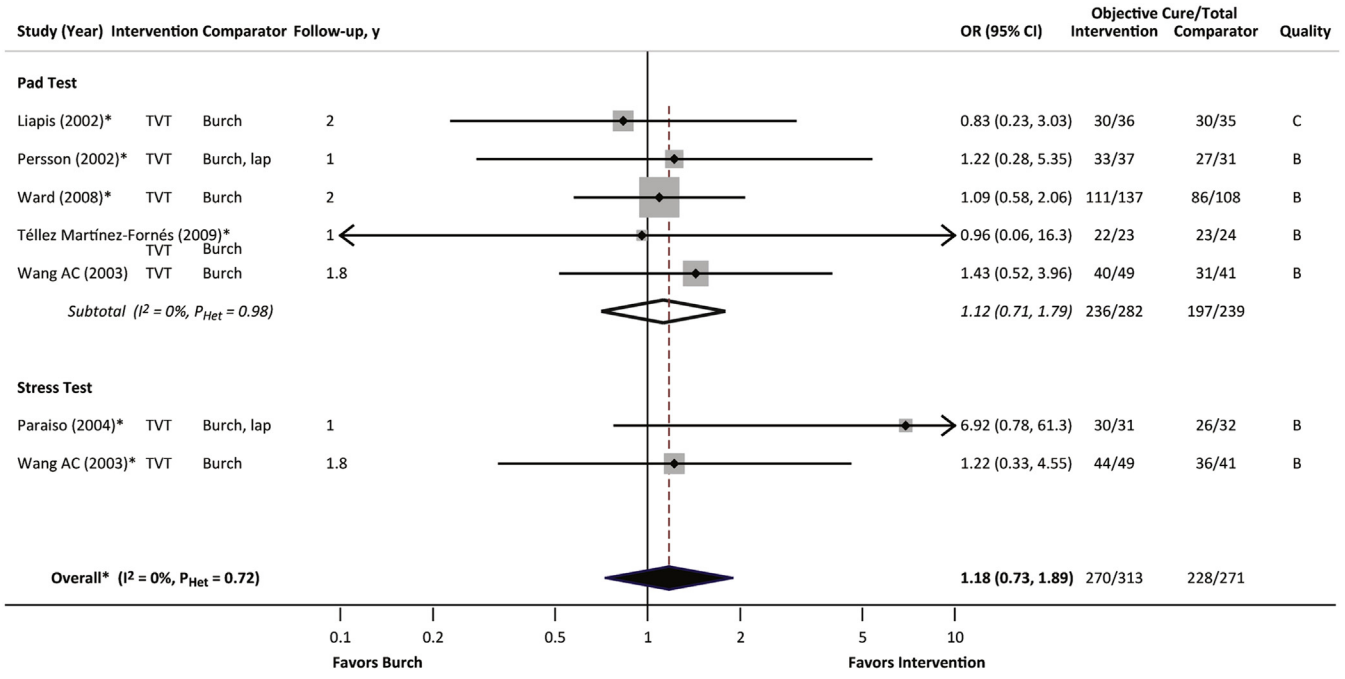
FIGURE 2
Metaanalysis for objective cure: MUS vs Burch urethropexy



Forest plot subdivided by objective cure test. *Gray boxes* reflect weight of each comparison in metaanalyses. All MUS used in trials were retropubic. See "Materials and Methods" for quality assessment scheme. Stress test chosen preferentially over pad test.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *lap*, laparoscopic; *MUS*, midurethral slings; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TVT*, tension-free vaginal tape.

*Studies included in overall metaanalysis.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

compared to Burch (OR, 1.18; 95% CI, 0.73–1.89) (Figure 2). The 6 RCTs that met inclusion for this outcome analyzed TVT vs Burch, which was performed open or laparoscopically.

For subjective cure, the metaanalysis included retropubic slings (all TVT) and obturator slings (unspecified obturator sling or Safyre T; Promedon, Cordoba, Argentina) (Figure 3). The pooled OR for all analyses showed no significant difference but favored slings compared to Burch (OR, 1.12; 95% CI, 0.79–1.60). Similar results were seen for metaanalyses of retropubic and obturator slings compared individually to the Burch procedure (Figure 3).

Metaanalysis for the satisfaction outcome was not possible due to a limited number of studies. Analysis of perioperative and AE data for the absolute rates of complications per type of surgery showed that MUS may result in lower rates of perioperative AEs such as postoperative pain, operating room time, hospital stay, bowel injury, wound infection, and hematomas (Appendix and Table 3). Burch procedures may result in lower rates of longer-term AEs such as return to the operating room for retention or erosion, overactive bladder (OAB) symptoms, and groin pain (Table 3). Metaanalysis of AE outcomes that were similar across studies showed no significant difference among these procedures for postoperative OAB symptoms, return to the operating room for erosion, and return to the operating room for retention. Interpretation of these rates is also dependent on the route of the MUS (obturator vs retropubic) that would be chosen, although more studies were available using retropubic slings for this comparison, weighting our analysis.

In summary, for women considering MUS or Burch procedures for treatment of SUI, we suggest either intervention for objective and subjective cure, with the decision based on AEs and other planned concomitant surgeries (vaginal vs abdominal route) (Table 4).

Pubovaginal slings vs Burch urethropexy

There were 4 RCTs for this comparison with an overall high quality of evidence (Supplementary Table 2).[9,19-21] The pubovaginal slings in these studies were composed of autologous fascia, Gore-Tex (Gore Medical, Flagstaff, AZ), or human dura mater.[9,19-21] The data for this grouping included the SISTEr trial, a high-quality, multicenter network trial with 655 subjects investigating autologous pubovaginal slings compared to Burch surgery (Table 1).[19] No studies reported sexual function data and only 1 reported quality-of-life outcomes.[19] The evidence favored sling procedures compared to Burch for subjective and objective cure outcomes.

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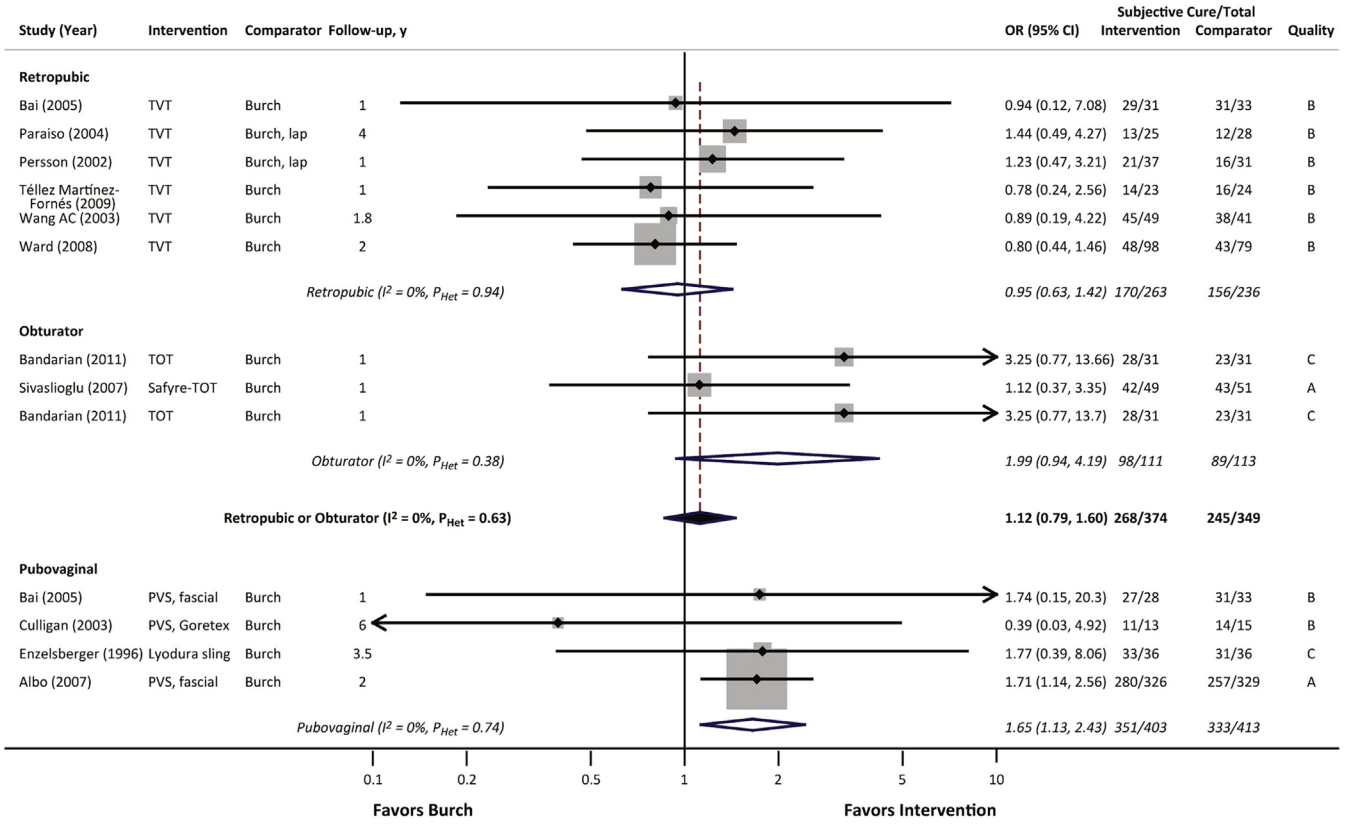
FIGURE 3
Metaanalysis for subjective cure: slings vs Burch urethropexy



Forest plots subdivided by slings being compared with Burch urethropexy. *Gray boxes* reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *lap*, laparoscopic; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *PVS*, pubovaginal sling; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

There was an inadequate number of studies to support a metaanalysis of objective cure. Subjective cure outcome metaanalysis favored pubovaginal sling compared to Burch (OR, 1.65; 95% CI, 1.13−2.43) (Figure 3).

Metaanalysis for the satisfaction outcome was not possible due to a limited number of studies. Looking at absolute rates of AEs per procedure, a Burch procedure results in lower rates of OAB symptoms, transfusion, hematomas, and return to the operating room for retention or erosion. Pubovaginal slings result in lower rates of wound infection, groin pain, urinary tract infection, and bladder/vaginal perforation. Metaanalysis of AE information showed no significant difference between the 2 surgeries for postoperative OAB symptoms and return to the operating room for erosion. There was a greater risk of return to the operating room for retention with the pubovaginal sling in the 2 studies that could be combined for this question (OR, 14.9; 95% CI, 1.35−165.15; $P = .028$).

In summary, for women considering pubovaginal slings or Burch procedures for treatment of SUI, we recommend pubovaginal slings to maximize cure outcomes (Table 4).

Pubovaginal slings vs MUS

There were 5 RCTs for this grouping and the evidence was overall of low quality (Supplementary Table 3).[9,22-25] The only MUS included in these studies was a retropubic TVT sling. There are no RCTs comparing pubovaginal slings to obturator MUS or minislings. No studies reported sexual function data. Review of the available data did not support a difference between procedures for either cure outcome.

Metaanalysis of data for subjective cure outcomes favors placement of MUS compared to pubovaginal slings (OR, 0.40; 95% CI, 0.18−0.85) (Figure 4). There were inadequate studies to support a metaanalysis for objective cure. Metaanalysis for the satisfaction outcome was also not possible due to a limited number of studies.

Comparing absolute complication rates for the surgeries in general, MUS resulted in lower rates of operating room time, blood loss, transfusion, wound infection, retention, OAB symptoms, and hospital stay (Appendix and Table 3). Interpretation of these rates is also dependent on the route of MUS (obturator vs retropubic) that would be chosen. Pubovaginal slings result in

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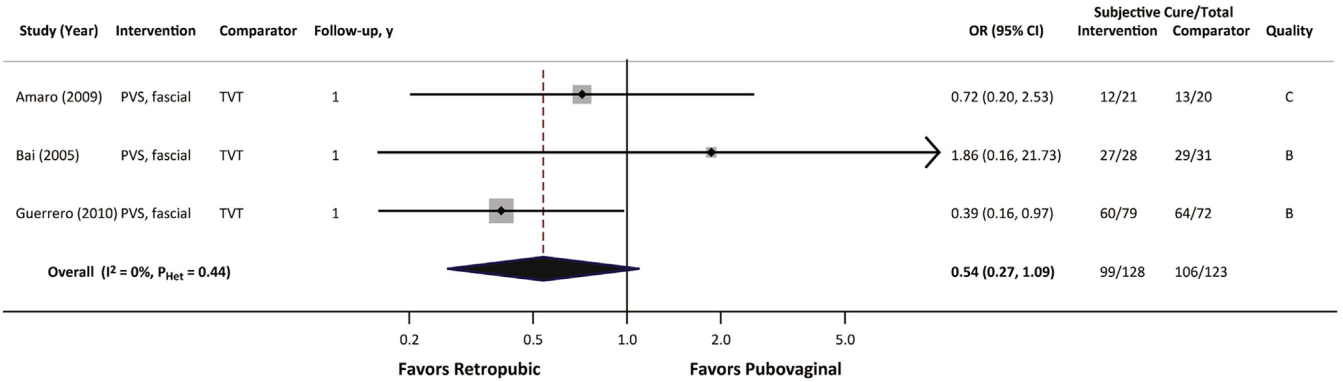
FIGURE 4
Metaanalysis for subjective cure: pubovaginal vs MUS



Gray boxes reflect weight of each comparison in metaanalyses. All MUS used in trials were retropubic. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *MUS*, midurethral slings; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *PVS*, pubovaginal sling; *TVT*, tension-free vaginal tape.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

lower rates of urinary tract infection and vaginal perforation than either route of MUS (Table 3). Metaanalysis of AE information showed no significant difference between these surgeries for postoperative OAB symptoms, return to the operating room for retention, or return to the operating room for erosion.

Driven by the metaanalysis information, for women considering a pubovaginal sling or MUS for treatment of SUI, we recommend MUS for better subjective cure (Table 4).

Retropubic MUS vs obturator MUS

This comparison had the most studies with 21 RCTs with large numbers of patients enrolled (Supplementary Table 4).[1,26-44] The quality of evidence was high, including Trial of Midurethral Slings (TOMUS), a high-quality multicenter network trial with 597 participants.[1] The evidence did not show a difference for objective or subjective cure outcomes between the 2 slings. Quality-of-life and sexual function outcomes were also similar between the 2 procedures.

Metaanalysis of objective cure data favored retropubic slings but was not significant (OR, 1.18; 95% CI, 0.95−1.47) (Figure 5). The retropubic sling studied was a TVT in all studies in the metaanalysis.

Similarly, for subjective cure, metaanalysis favored retropubic slings (OR, 1.17; 95% CI, 0.91−1.51) but was not significant (Figure 6). Again, the retropubic sling for included studies was always a TVT while the obturator slings included a variety of slings and routes of passages.

Four studies were included in a metaanalysis of satisfaction outcomes (Figure 7), which favored obturator slings but was not significant (OR, 0.77; 95% CI, 0.52−1.13).

AE and perioperative outcome data were highly variable by each outcome and did not provide a consistent direction when examined by absolute rates of complications for each surgery (Appendix and Table 3). Retropubic slings result in lower absolute rates of sling erosion, need to return to the operating room for treatment of sling erosion, nerve injury, ureteral injury, groin/leg pain, and vaginal perforation. Obturator MUS result in shorter operative time, lower blood loss, fewer bladder/urethral perforations, less perioperative pain, fewer urinary tract infections, and less OAB symptoms. Metaanalysis showed that postoperative OAB symptoms were more common in patients following retropubic slings (OR, 1.41; 95% CI, 1.01−1.98, $P = .046$). There was no difference between slings on metaanalysis of return for operating room for erosion or for retention. There were too few studies that examined subpopulations of stress-incontinent patients (eg, those with intrinsic sphincter deficiency or prior surgical failures) to allow metaanalysis.

In summary, for women considering a retropubic or transobturator MUS, we recommend either intervention for objective and subjective cure; the decision should be based on surgeon expertise accounting for AEs (Table 4).

Retropubic MUS vs retropubic MUS

There was a limited number (2) of RCTs for this question, and moderate-quality evidence (Table 1) (Supplementary Table 5).[45,46] These studies each compared top-down passage (SPARC; AMS, Minnetonka, MN) to bottom-up passage (TVT). The evidence does not support a difference in outcomes between the retropubic slings studied. No studies reported quality-of-life or sexual function data.

Because we collected AE data by sling type (eg, retropubic vs obturator slings), we could not segregate complications by route of passage.

There were inadequate data to support any metaanalyses. The evidence was also not robust enough to merit a clinical practice guideline.

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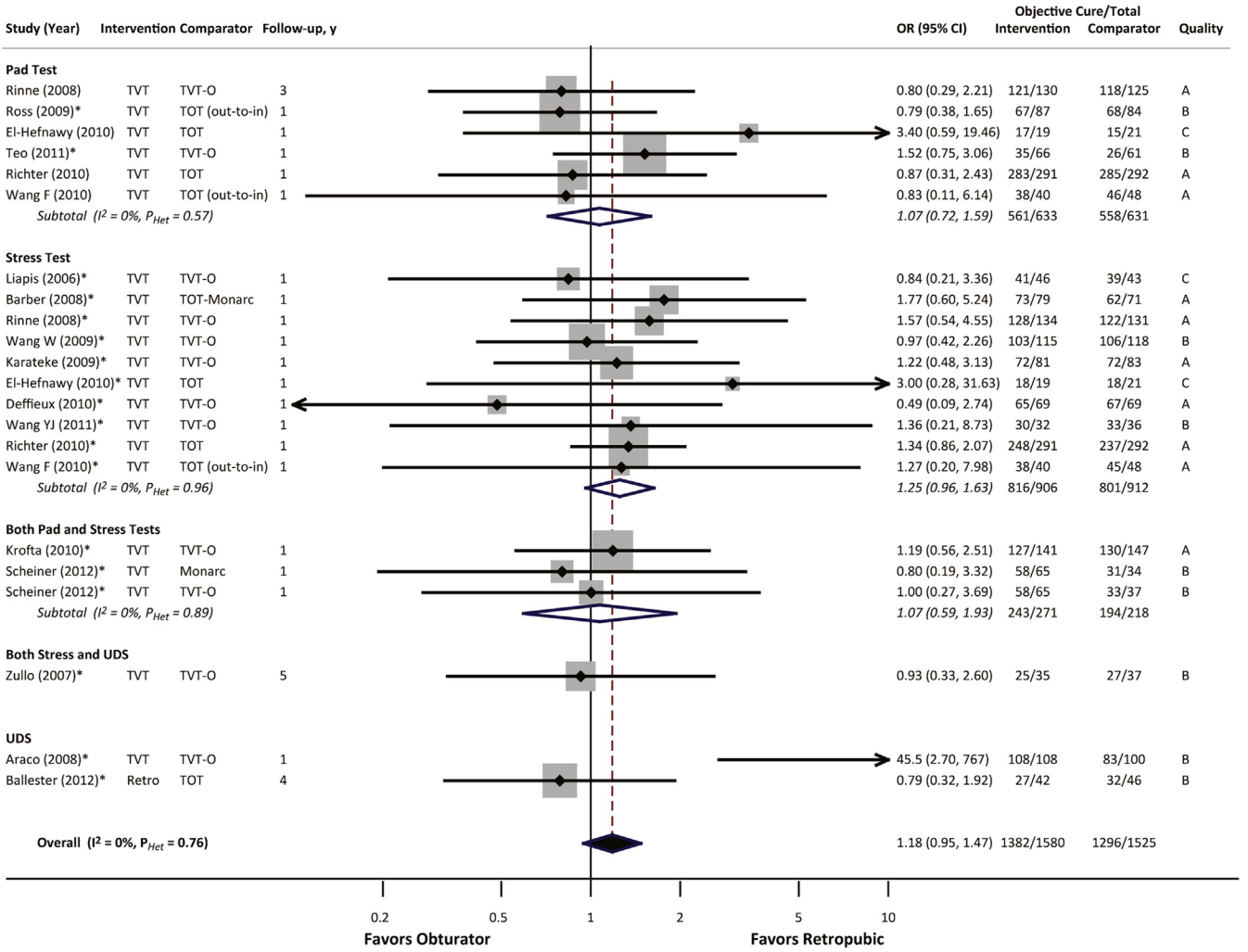
FIGURE 5
Metaanalysis for objective cure: retropubic (retro) vs obturator midurethral slings



Forest plot subdivided by objective cure test. *Gray boxes* reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme. Stress test chosen preferentially over pad test.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator; *UDS*, urodynamic study.

*Studies included in overall metaanalysis.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

Obturator MUS vs obturator MUS

There have been 2 RCTs investigating this question, which provided low-quality evidence (Table 1) (Supplementary Table 6).[39,47] The evidence does not support a difference in outcomes between the routes of obturator slings studied.

Because we collected AE data by sling type (eg, retropubic vs obturator slings), we could not segregate complications by route of passage.

There were inadequate data to support any metaanalyses. The evidence was also not robust enough to merit a clinical practice guideline.

Minislings vs any other slings

There were 15 RCTs providing data for this question, which represented 3-arm or 2-arm studies by original design (Table 1) (Supplementary Table 7).[43,48-56] The comparator arm of traditional full-length MUS was either an obturator or retropubic sling; no studies compared Burch urethropexy or pubovaginal slings to minislings. The majority of studies in this category used a TVT-Secur (Ethicon Gynecare, Cincinnati, OH) placed in either the "U" (similar to retropubic slings) or "H" (similar to obturator slings) configuration. While this product is no longer available in the United States, it was retained for this analysis because we thought that there was significant interest among physicians regarding this clinical question. By excluding studies with TVT-Secur (Ethicon Gynecare) from the analysis, a review and guideline on this question would not have been possible.

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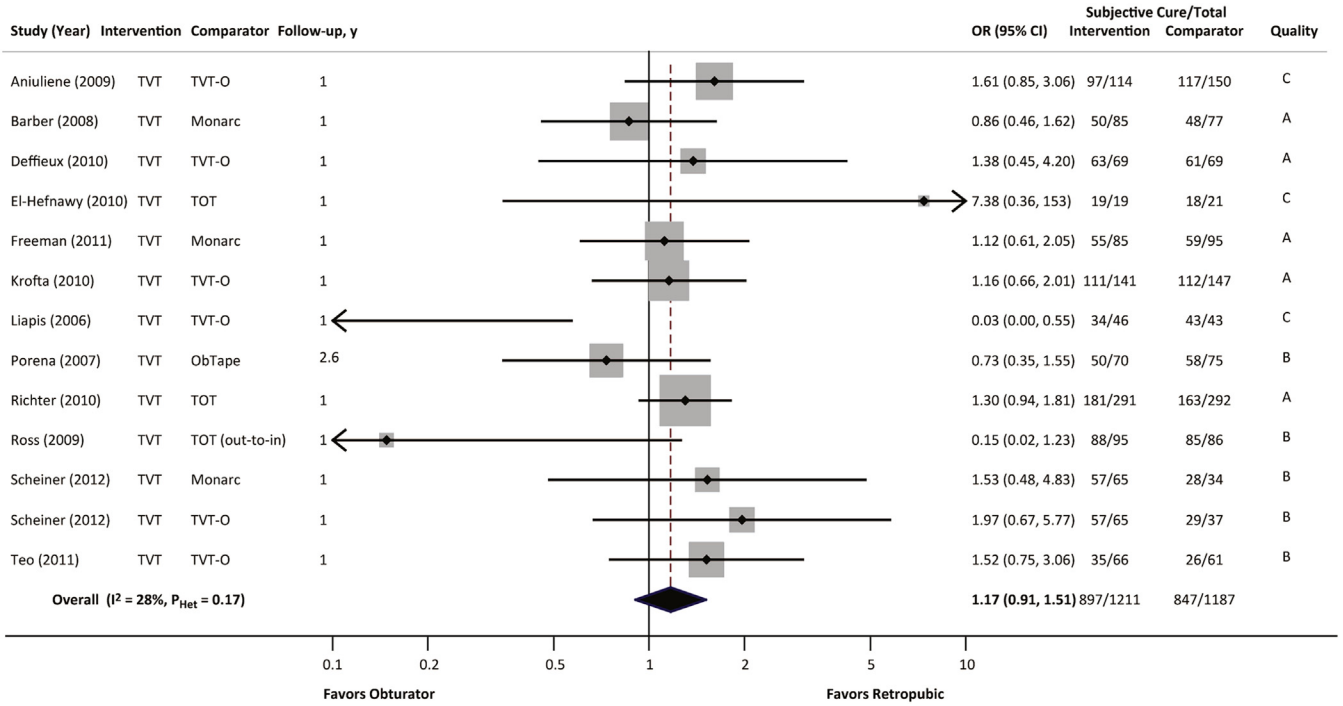
FIGURE 6
Metaanalysis for subjective cure: retropubic vs obturator midurethral slings



Gray boxes reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

Review of the evidence showed that both objective and subjective cure outcomes were improved with use of a full-length sling compared to a minisling.

Metaanalysis of objective cure outcomes significantly favored traditional full-length MUS, all of which happened to be an obturator sling (TVT-obturator), compared to minislings (OR, 4.16; 95% CI, 2.15–8.05) (Figure 8).

Results were similar for the metaanalysis of subjective cure outcomes (Figure 9). There were data included for both obturator and retropubic traditional MUS. Traditional MUS were found to be superior to minislings (OR, 2.65; 95% CI, 1.36–5.17).

Metaanalysis for the satisfaction outcome was not possible due to a limited number of studies.

With respect to a comparison of AEs, the route (retropubic vs obturator) of the traditional full-length MUS is an important consideration (Table 3). For example, minislings have similar rates of postoperative OAB symptoms (5.4%) compared with obturator slings (5.3%), but somewhat lower rates than retropubic slings (6.9%). Exposure of the sling postoperatively is similar with either obturator slings (2.2%) or minislings (2.0%), but retropubic slings have somewhat lower rates than either (1.4%). Dyspareunia is rare with any type of sling, but is somewhat more common with a minisling (0.99%) than either a retropubic (<0.001%) or obturator (0.16%) sling. Minislings have the highest rate of urethral perforation (2.7% vs <1% for either retropubic or obturator), but the lowest rate of groin pain (0.62%) when compared to either route of MUS (1.5% for retropubic, 6.5% for obturator). Metaanalyses of the AE data failed to show a significant difference for OAB symptoms after surgery or return to the operating room for retention.

In summary, for women considering minislings or traditional full-length MUS, we recommend traditional full-length MUS to maximize cure rates (Table 4).

Comment

Surgical treatment of SUI has been well studied. MUS have become more common than pubovaginal sling procedures and Burch urethropexy for correction of SUI. In this systematic review we reviewed studies comparing MUS (retropubic, obturator, and minisling), pubovaginal slings, and Burch urethropexy for treatment of SUI in women. A large number of studies were available for review. In general, both the quality of study design and the inclusion of patient-centered outcomes have improved over time. We found low- to high-quality evidence permitting metaanalyses and development of clinical practice guidelines.

The best-studied comparison is for retropubic compared to obturator MUS, which included 21 separate studies. There appears to be little need to study

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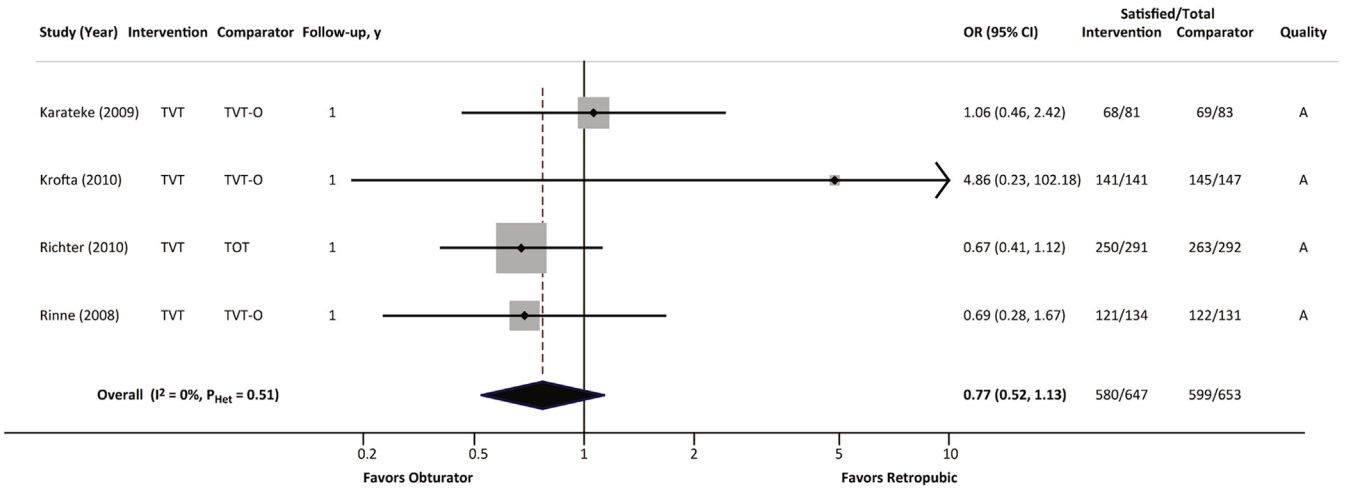
FIGURE 7
Metaanalysis for satisfaction: retropubic vs obturator midurethral slings



Gray boxes reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TOT*, transobturator sling; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

this further for straightforward SUI unless surgical products change significantly. We found few reliable data for subpopulations; patients who have urethral sphincter weakness or a history of surgical failure, for example, are often analyzed together with primary surgical candidates with normal urethral function. Definitions of these conditions were highly variable, which meant we were not able to perform reliable analyses of these data. As these are challenging populations to treat clinically, they should be better studied in future work. There is 1 trial that exclusively enrolled women with intrinsic sphincter deficiency, defined either by maximum urethral closure pressure of <20 cm H_2O or leak point pressures of <60 cm H_2O.[39,76,77] While urodynamic stress incontinence 6 months postoperatively was more common in patients undergoing an obturator sling, objective cure rates based on pad test at 6 months, perioperative information, overall definition of "success," and sexual function data showed no difference between slings.[39,76,77] For subjective cure rates, the obturator sling was favored only on analysis of Incontinence Impact Questionnaire-7 total score data at 3 years' follow-up, with other markers and time periods for subjective cure measures not different between groups.[39,76,77] Rate of reoperation for SUI at 3 years of follow-up favored the retropubic sling in this population (18.3% of women in obturator sling group vs 1.2% of the women in the retropubic sling group on intention-to-treat analysis, $P<.001$) with a significantly shorter time to reoperation in the obturator group as well.[39,76,77]

Comparing MUS vs Burch urethropexy, there is moderate-quality evidence that either procedure provides equivalent subjective and objective cure rates. The benefits of a minimally invasive approach may be offset by the inclusion of concomitant procedures. For example, if other intraabdominal procedures are planned, this may mitigate the perioperative differences and AEs associated with Burch surgery compared to a MUS.

Only one study compared different types of pubovaginal slings to each other based on the type of sling material, and therefore we could not draw any conclusions on this question.[57]

We eliminated studies with <12 months' follow-up because of the robust body of literature on this topic (Table 1 presents length of follow-up for each study). Still, it is worthy to note that this is short-term from the perspective of a patient who desires lifelong cure. While challenging from an investigator standpoint, more studies with extended follow-up are needed.

One challenge in creation of clinical practice guidelines came when the importance of the various outcomes was weighed against each other. For example, should objective cure be more important overall than postsurgical sexual function? Many studies used composite success outcomes in an attempt to address this issue. The weight of these factors may also differ for surgeons and patients, and even between patients. For this reason, the clinical practice guideline statements provide detail to guide physician-patient counseling, which remains of paramount importance when planning surgery. Counseling also should address the impact of other concomitant procedures, such as hysterectomy and pelvic organ prolapse repair, in the decision-making process among the options for incontinence treatment.

Despite being the newest product on the market, the minislings had a large number of studies that met our inclusion criteria. Considering the interest in these slings, we thought it was merited to include TVT-Secur (Ethicon Gynecare)

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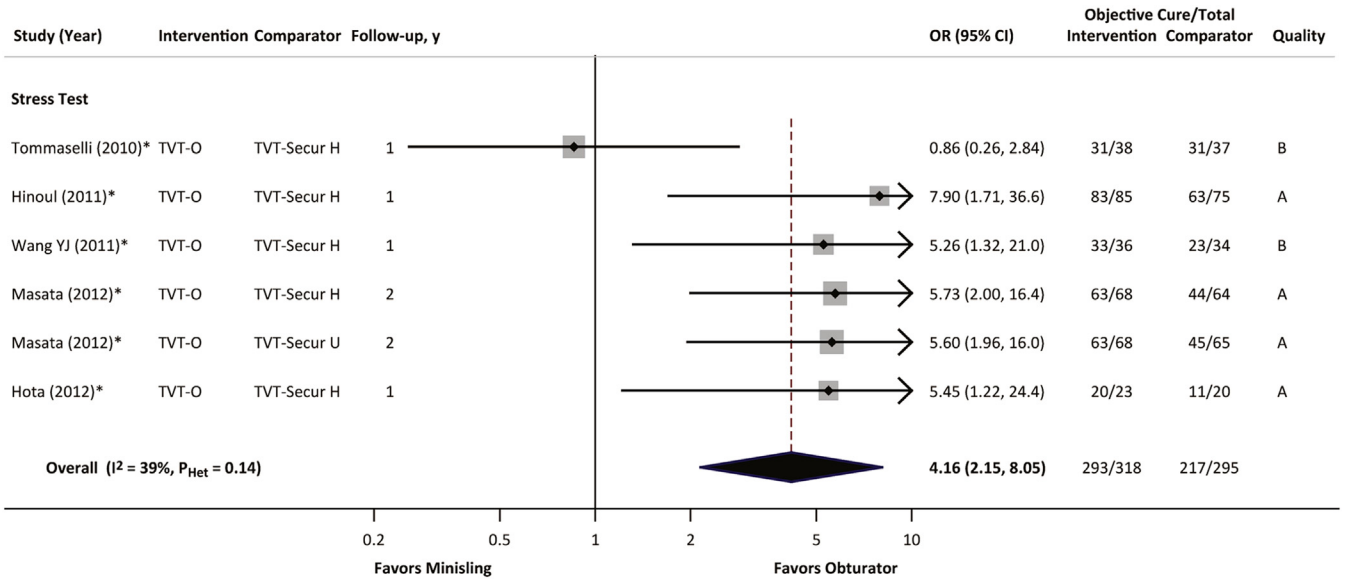
FIGURE 8
Metaanalysis for objective cure: traditional midurethral sling (MUS) vs minisling



Gray boxes reflect weight of each comparison in metaanalyses. All MUS used in trials were retropubic. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *MUS*, midurethral slings; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

*Studies included in overall metaanalysis.

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in our analysis although it has now been removed from the market. It should be noted that this is the most widely studied minisling, and the results of those studies and thus our review may not be generalizable to newer products. Further RCTs on these newer products are needed.

When choosing between surgical procedures, any surgeon must weigh the presumed benefits with the potential risks and AEs of these procedures. Balancing those against a specific patient's goals and desires is an important consideration for a diagnosis such as SUI in which treatment is elective based on degree of bother and quality-of-life impact. Additionally, surgeons should evaluate their own personal success and complication rates with the procedures and products they use, as these may differ from published rates. Whenever possible, physicians should counsel patients about the balance of both success rates and AEs for the various procedures discussed in this review. For example, some patients may tolerate some mild SUI to avoid any risk of obstructive OAB symptoms, while other patients would accept a high risk of needing to self-catheterize to avoid any SUI.

The strengths of this review include the large numbers of randomized clinical trials reviewed to provide data for the metaanalyses and clinical practice guidelines. Most of the randomized trials achieved their stated power and some studies reported long-term follow-up extending up to 5 years. Given the breadth of these data, we thought we could limit our review to studies with data at 12 months or longer, since patients and surgeons place higher value on long-term success rather than shorter-term rates. Our strict inclusion criteria, including the length of follow-up and the exclusion of meeting abstracts not submitted to the peer-review process, makes the included outcome data strong. There were also a large number of comparative cohort studies and observational studies to provide data on AEs. We were able to limit our collection to those studies with often >1000 patients to collect the most common problems rather than basing conclusions on rare, unusual events from smaller studies or case reports.

There are limitations to the study. Reporting of subpopulations of high interest to surgeons, including intrinsic sphincter deficiency and recurrent SUI, were variable and often not separated out from other patients in analyses, so we cannot draw conclusions about those populations. There was also high variability in reporting of numbers and types of complications in trials, making analyses of AE outcomes challenging. While many surgeons and patients are interested in information about postoperative symptoms such as urgency and de novo urgency, these symptoms were inconsistently reported, thus limiting their analysis. Additionally, data concerning need for retreatment were sparse and inconsistent, limiting our ability to draw any conclusions on this important question. Complications were assessed at different time intervals among different trials, and sometimes later trials reporting secondary analyses did not update longer-term AEs. The vast

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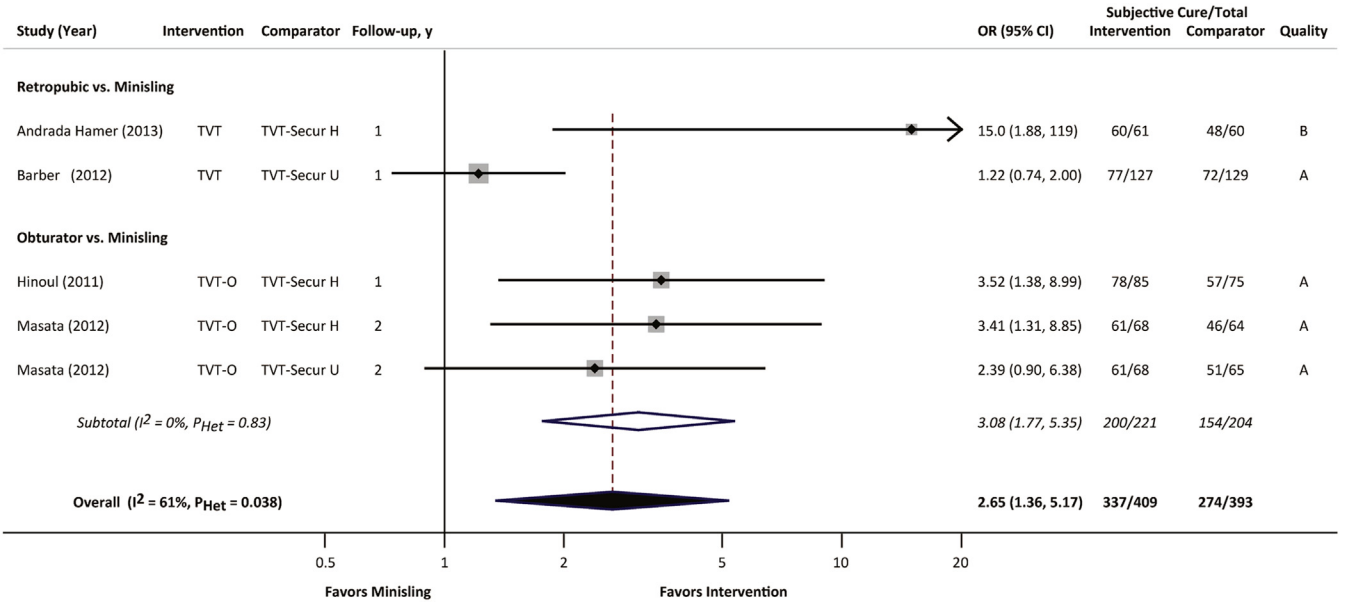
FIGURE 9
Metaanalysis for subjective cure: traditional midurethral sling vs minisling



Forest plot subdivided by slings being compared with minisling. *Gray boxes* reflect weight of each comparison in metaanalyses. See "Materials and Methods" for quality assessment scheme.

CI, confidence interval; I^2, percentage of total variation across studies that is due to heterogeneity rather than chance; *OR*, odds ratio; P_{Het}, χ^2 *P* value for statistical heterogeneity; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape-obturator.

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majority did not use a standard classification for complications such as the classification system of Dindo et al.[58] The length of follow-up for outcomes in most RCTs was up to 5 years but there was attrition as length of follow-up increased, which reduced the numbers of patients analyzed to determine long-term success rates for the slings or Burch urethropexy. Retropubic MUS, specifically TVT, is the best-studied procedure. There were few studies comparing different types of retropubic slings, obturator slings, or pubovaginal slings within those classifications, limiting our ability to comment on the best product/material.

In summary, this review supports the use of MUS for treatment of SUI compared to pubovaginal slings. The decision for retropubic vs obturator approaches to MUS may be based on the risks associated with each approach as no difference in effectiveness was found. The pubovaginal sling procedure is more effective than Burch urethropexy although, again, differences in surgical risks may guide the decision to utilize one approach over the other. Traditional MUS are significantly superior to minislings for cure outcomes. Overall, the evidence supporting use of MUS and pubovaginal slings is of high quality. These clinical practice guidelines provide an effective tool to assist in patient counseling and decision-making for the various surgical approaches to management of SUI. ■

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Appendix

SUPPLEMENTARY TABLE 1
Evidence profile for midurethral sling vs Burch

Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Summary of findings: Evidence strength	Summary of findings: Effect	Summary of findings: Outcome importance
Objective cure	9	994	1A (0), 4B (-1), 2B (-2), 2C (-2)	0	0	0	Moderate	No difference	Critical
Subjective cure	8	712	1A (-1), 2B (-1), 2B (-2), 3C (-2)	0	0	0	Moderate	No difference	Critical
Perioperative outcomes	9	964	1A (0), 4B (-1), 1B (-2), 3C (-2)	0	0	0	High	Favors midurethral	Variable
Quality of life	3	465	3B (-1)	0	0	0	Moderate	No difference	Critical
Sexual functioning	1	344	1B (-1)	NA	0	-1	Low	No difference	High
Total	10 separate studies								

Quality of overall evidence: moderate. Balance of benefits and harms: comparing midurethral slings (retropubic or obturator routes) to Burch (open or laparoscopic), there were no differences in objective or subjective cure, quality of life and sexual function outcomes. Metaanalyses for subjective and objective cure also showed no significant differences. There were not enough studies to perform a metaanalysis of subjective cure outcomes. Perioperative outcomes favored midurethral slings but long-term adverse event outcomes were less common with the Burch procedure. Metaanalysis of the adverse event outcomes where possible did not show a difference.

NA, not applicable.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 2
Evidence profile for PV sling vs Burch

Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Summary of findings: Evidence strength	Summary of findings: Effect	Summary of findings: Outcome importance
Objective cure	4	855	1A (0), 1B (-2), 1B (-1), 1C (-2)	0	0	0	High	Favors sling	Critical
Subjective cure	2	747	1A (0)	NA	0	0	High	Favors sling	Critical
Perioperative outcomes	3	819	1A (0), 1B (-1), 1C (-2)	0	0	0	High	Favors Burch	Variable
Quality of life	1	655	1A (0)	NA	0	0	High	No difference	Critical
Sexual functioning	0	0	NA	NA	NA	NA	NA	NA	High
Total	4 separate studies								

Quality of overall evidence: high. Balance of benefits and harms: comparing PVS using fascia or synthetic material to Burch (open or laparoscopic) for SUI treatment, objective and subjective cure outcomes favor PVS. There was no difference seen for quality of life outcomes and no data regarding sexual functioning. Short-term (perioperative) and long-term adverse event outcomes favor Burch although some adverse events are less common with sling procedures.

NA, not applicable; *PVS*, pubovaginal slings; *SUI*, stress urinary incontinence.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

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SUPPLEMENTARY TABLE 3

Evidence profile for pubovaginal sling vs midurethral sling

							Summary of findings		
Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Evidence strength	Effect	Outcome importance
Objective cure	3	233	1B (-1), 1B (-2), 1C(-2)	0	0	0	Low	No difference	Critical
Subjective cure	4	305	2B (-2), 1C (-2)	0	0	0	Very low	No difference	Critical
Perioperative outcomes	4	383	2B (-1), 2C (-2)	-1	0	0	Low	Favors midurethral	Variable
Quality of life	3	342	2B (-1), 1C (-2)	0	0	0	Low	No difference	Critical
Sexual functioning	0	0	NA	NA	NA	NA	NA	NA	High
Total	5 separate studies								

Quality of overall evidence: low. Balance of benefits and harms: comparing PVS (fascia or synthetic material) to synthetic midurethral slings (only retropubic passage was studied), objective and subjective cure outcomes as well as quality of life and sexual function outcomes showed no differences. There were not enough studies available to perform a metaanalysis for objective cure outcomes, but a metaanalysis for subjective cure significantly favored midurethral slings. Both short-term (perioperative) and long-term adverse event data in general favored midurethral slings although metaanalysis did not show a difference for selected adverse-event outcomes.

NA, not applicable; *PVS*, pubovaginal slings.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 4

Evidence profile for retropubic vs obturator sling

							Summary of findings		
Outcome	**No. studies**	**Total n**	**Methodological quality**	**Consistency**	**Directness**	**Other considerations**	**Evidence strength**	**Effect**	**Outcome importance**
Objective cure	19	3354	7A (0), 6B (-1), 4B (-2), 2C (-2)	0	0	0	High	No difference	Critical
Subjective cure	18	3186	6A (0), 2A (-1), 4B (-1), 2B (-2), 2C (-2)	0	0	0	High	No difference	Critical
Perioperative outcomes	21	3811	8A (0), 10B (-1), 3C (-2)	-1	0	0	High	Most outcomes show no difference but wide range. For OR time, 10 studies show a difference and 8 favor obturator>retropubic. One study demonstrated that obturator sling patients were in hospital less time. For pain, 3 studies show a difference, 1 favoring retropubic and 2 favoring obturator.	Variable
Quality of life	15	2837	8A (0), 7B (-1)	0	0	0	High	No difference	Critical
Sexual functioning	10	2004	4A (0), 1A (-1), 4B (-2), 1B (-1)	0	0	0	High	No difference	High
Total	21 separate studies								

Quality of overall evidence: high. Balance of benefits and harms: comparing retropubic to obturator midurethral slings, there was no difference seen for objective cure, subjective cure, quality of life or sexual functioning outcomes. Metaanalysis favored retropubic slings for objective and subjective cure, although neither was significant. Metaanalysis for satisfaction favored obturator slings, but again was not significant. Adverse event data was variable across outcomes. Metaanalysis showed postoperative overactive bladder symptoms were more common with retropubic slings, but rates of retention and return to OR for erosion were similar.

OR, operating room.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

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SUPPLEMENTARY TABLE 5

Evidence profile for retropubic vs retropubic sling

							Summary of findings		
Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Evidence strength	Effect	Outcome importance
Objective cure	2	146	2B (-1)	0	0	0	Moderate	No difference	Critical
Subjective cure	1	84	1B (-1)	NA	0	-1	Low	No difference	Critical
Perioperative outcomes	2	146	2B (-1)	0	0	0	Moderate	No difference	Moderate
Quality of life	0	0	NA	NA	NA	NA	NA	NA	Critical
Sexual functioning	0	0	NA	NA	NA	NA	NA	NA	High
Total	2 separate studies	146							

Quality of overall evidence: low. Balance of benefits and harms: comparing TVT (retropubic *bottom-up*) to SPARC (AMS, Minnetonka, MN) (retropubic *top-down*) in a population undergoing both prolapse repairs and anti-incontinence procedures, it is uncertain whether TVT is preferable to SPARC. There were few studies to analyze. Similar objective cure, perioperative event, and long-term adverse event rates (moderate quality evidence) and subjective cure rates (low quality evidence) are observed for TVT and SPARC. Data are insufficient to compare differences in postoperative QoL or sexual function. Adverse events could not be compared.

NA, not applicable; *QoL*, quality of life; *TVT*, tension-free vaginal tape.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 6

Evidence profile for obturator vs obturator sling

							Summary of findings		
Outcome	No. studies	Total n	Methodological quality	Consistency	Directness	Other considerations	Evidence strength	Effect	Outcome importance
Objective cure	2	421	2B (-1)	NA	0	-1	Low	No difference	Critical
Subjective cure	2	421	1B (-1) 1B (-2)	NA	0	-1	Low	No difference	Critical
Perioperative outcomes	1	80	1B (-1)	NA	0	-1	NA	NA	Variable
Quality of life	2	421	2B (-1)	NA	0	-1	Low	No difference	Critical
Sexual functioning	2	421	1B (-1) 1B (-2)	NA	0	-1	Low	No difference	High
Total	2 studies								

Quality of overall evidence: low. Balance of benefits and harms: in 2 studies comparing routes of obturator sling passage (in-to-out vs out-to-in) for SUI, it is uncertain which route is preferable. Similar objective cure, subjective cure, quality of life and sexual functioning results were seen with low-quality evidence. Data are insufficient to compare short- or long-term adverse events.

NA, not applicable; *SUI*, stress urinary incontinence.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

SUPPLEMENTARY TABLE 7

Evidence profile for minisling vs other

							Summary of findings		
Outcome	**No. studies**	**Total n**	**Methodological quality**	**Consistency**	**Directness**	**Other considerations**	**Evidence strength**	**Effect**	**Outcome importance**
Objective cure	15	1916	7A (0), 1B (-1), 4B (-2), 3C (-2)	-1	0	0	High	Favors other sling over minisling	Critical
Subjective cure	9	1516	3A (0), 4A (-1), 1B (-1), 1B (-2)	-1	0	0	High	Favors other sling over minisling	Critical
Perioperative outcomes	15	1916	7A (0), 5B (-1), 3C (-2)	-1	0	0	Moderate	For EBL, no difference in most studies. For catheter time favors TVT-O or no difference. For pain, favors minisling. Hospital time not different. OR time results mixed.	Variable
Quality of life	9	1467	7A (0), 2B (-1)	0	0	0	Moderate	No difference	Critical
Sexual functioning	3	708	1A (0), 2B (-1)	0	0	sparse	Moderate	No difference	High
Total	15 arms								

Quality of overall evidence: high. Balance of benefits and harms: Comparing traditional MUS (TVT or TVT-O) to the minislings (TVT-Secur U or H position, MiniArc), both objective and subjective cure outcomes strongly favored the traditional MUS, including on metaanalyses of both types of cure outcomes. No difference was seen for quality of life or sexual functioning outcomes. Adverse event outcomes were mixed and may depend on which MUS passage would be chosen as an alternative; metaanalysis of adverse-event data showed no difference. MiniArc; AMS, Minnetonka, MN; TVT-Secure; Ethicon Gynecare, Cincinnati, OH.

EBL, estimated blood loss; *MUS*, midurethral slings; *TVT*, tension-free vaginal tape; *TVT-O*, tension-free vaginal tape obturator.

Schimpf. Sling surgery for stress urinary incontinence. Am J Obstet Gynecol 2014.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

DIANNE M. BELLEW,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-22473

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

The following motions have been brought by the defendants, Ethicon, Inc. and Johnson & Johnson (collectively, "the defendants"): (1) Motion to Exclude or, Alternatively, to Limit the Opinions and Testimony of Dr. Howard Jordi, Ph.D. [Docket 118]; (2) Motion to Exclude the Opinions and Testimony of Prof. Dr. –Ing. Thomas Mühl [Docket 107]; (3) Motion to Limit the Testimony of Prof. Dr. Med. Uwe Klinge [Docket 101]; (4) Motion to Exclude Certain Opinions of Daniel S. Elliott, M.D. [Docket 116]; and (5) Motion to Exclude the Testimony of Dr. Vladimir Iakovlev, M.D. [Docket 121].

The following motions have been brought by the plaintiff, Dianne M. Bellew: (1) Motion to Preclude the Testimony of Defense Expert David J. Weber, M.D., M.P.H. [Docket 114]; (2) Motion to Preclude the Testimony of Defense Expert Denise M. Elser, M.D. on the Adequacy of Defendants' Warnings and Pre-Existing Myalgia [Docket 127]; (3) Motion to Preclude the Testimony of Defense Expert Christina Pramudji, M.D. on Particular Issues; and (4) Motion to Preclude Testimony of Defense Expert Stanley J. Robboy, M.D., F.C.A.P. [Docket 131].

For the reasons explained below, the defendants' motion with respect to Dr. Jordi [Docket 118] is **DENIED as moot in part** and **DENIED in part**. The defendants' motion with respect to Dr. Mühl [Docket 107] is **DENIED**. The defendants' motion with respect to Dr. Klinge [Docket 101] is **DENIED as moot, DENIED in part**, and **GRANTED in part**. The defendants' motion with respect to Dr. Elliott [Docket 116] is **GRANTED in part, DENIED as moot in part, DENIED in part** and **RESERVED in part**. The defendants' motion with respect to Dr. Iakovlev [Docket 121] is **DENIED as moot in part, GRANTED in part**, and **DENIED in part**.

The plaintiff's motion with respect to Dr. Weber [Docket 114] is **DENIED**. The plaintiff's motion with respect to Dr. Elser [Docket 127] is **GRANTED**. The plaintiff's motion with respect to Dr. Pramudji [Docket 129] is **GRANTED in part** and **DENIED in part**. The plaintiff's motion with respect to Dr. Robboy [Docket 131] is **DENIED**.

I. Background

This bellwether case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 67,000 cases currently pending, approximately 22,000 of which are in the Ethicon, Inc. MDL, MDL 2327. In this particular case, the plaintiff was surgically implanted with the Prolift Anterior Pelvic Floor Repair System ("Prolift"), a mesh product manufactured by Ethicon and Johnson & Johnson (collectively, "Ethicon") to treat POP. (*See* Short Form Compl. [Docket 1], at 2).[1] The plaintiff received her surgery in Arizona. (*Id.* at 3). The plaintiff claims that as a result of implantation of the Prolift, she has experienced multiple complications, including mesh

[1] I have selected this case as a Prolift bellwether case in the Ethicon MDL. (*See* Pretrial Order # 98 [Docket 29], at I).

erosion, mesh contraction, inflammation, dyspareunia (pain during sexual intercourse), urinary incontinence, chronic pain, and recurring prolapse of organs. (Master Compl. ¶ 49). In addition, she had four additional operations to remove and revise the mesh. (Pl. Fact Sheet [Docket 206-1], at 7). The plaintiff alleges negligence, failure to warn, design defect, common law fraud, fraudulent concealment, negligent misrepresentation, breach of express warranty, violation of consumer protection laws, gross negligence, and punitive damages. (Short Form Compl. [Docket 1], at 4; *see also* Pl.'s Opp. to Defs.' Mot. for Summ. J. [Docket 153], at 1 n.1 (stating that the plaintiff will not pursue several of the claims set forth in her short form complaint)). The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions and testimony pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper.[2] It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see*

[2] With more than 67,000 cases related to surgical mesh products currently pending before me, this gatekeeper role takes on extraordinary significance. Each of my evidentiary determinations carries substantial weight with the remaining surgical mesh cases. Regardless, while I am cognizant of the subsequent implications of my rulings in these cases, I am limited to the record and the arguments of counsel.

also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Finally, in several of the instant *Daubert* motions, a specific scientific methodology comes into play, dealing with differential diagnoses or etiologies. "Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262. The Fourth Circuit has stated that:

> A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. A reliable differential diagnosis passes scrutiny under *Daubert*. An unreliable differential diagnosis is another matter:

> A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on

> causation. However, "[a] medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." The alternative causes suggested by a defendant "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony," unless the expert can offer "no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause."

Id. at 265–66 (internal citations omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire,* 526 U.S. at 152).

Before I review these motions, I begin by addressing three arguments that apply to many of the parties' *Daubert* objections. First, as I have maintained throughout these MDLs, I will not permit the parties to use experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's state of mind or on whether a party acted reasonably. *See, e.g., Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, at *3 (S.D. W. Va. July 8, 2014); *Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013). Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.

Second, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562

(4th Cir. 2006). I have diligently applied this rule to previous expert testimony, and I continue to adhere to it in this case. I will not parse the expert reports and depositions of each expert in relation to these same objections. I trust that able counsel in this matter will tailor expert testimony at trial accordingly.

Last, with respect to the arguments that certain experts' testimony is litigation driven, I note that an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion. *See Daubert v. Merrell Dow Pharm., Inc.* ("*Daubert II*"), 43 F.3d 1311, 1317 (9th Cir. 1995) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture."). This concern, however, does have a role in applying *Daubert*. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007) (considering in the *Daubert* analysis "[w]hether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" (quoting Fed. R. Evid. 702 advisory committee's note)). In sum, I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. But I will consider the independence of an expert's testimony as evidence that his "research comports with the dictates of good science." *Daubert II*, 43 F.3d at 1317. Having addressed these universal objections, I now turn to the defendants' *Daubert* motions.

III. The Defendants' *Daubert* Motions

In this case, the defendants seek to limit or exclude the expert opinions of Dr. Howard Jordi, Dr. Thomas Mühl, Dr. Uwe Klinge, Dr. Daniel S. Elliott, and Dr. Vladimir Iakovlev.

A. Motion to Exclude or, Alternatively, to Limit the Opinions & Testimony of Dr. Howard Jordi, Ph.D.

The defendants seek to exclude or limit the expert opinions of Dr. Howard Jordi, Ph.D. Dr. Jordi is a biochemist who founded Jordi Labs, which "provide[s] high quality analytical services to the polymer and plastics industry." (Jordi Report [Docket 135], at 1). He also served as president and CEO of Jordi Labs from 1980 to 2008. (*Id.*). The plaintiff offers Dr. Jordi to testify that (1) polypropylene degrades; (2) as a result of the chemical and physical degradation that occurs while in the body, the Prolift mesh fibers become brittle and crack; and (3) Ms. Bellew's explanted Prolift mesh degraded and cracked while in her body. (Pl.'s Resp. in Opp. to Defs.' Mot. & Mem. of Law to Exclude or, Alternatively, to Limit the Ops. & Test. of Dr. Howard Jordi, Ph.D. ("Pl.'s Resp. re: Jordi") [Docket 157], at 2). The defendants contend that Dr. Jordi should be prohibited from testifying about degradation entirely, but that in the alternative, the court should exclude his opinions regarding: (1) any clinical or mechanical effects of degradation; (2) degradation beyond the surface of the Prolene fibers; (3) mesh explants taken from patients other than the plaintiffs; (4) environmental stress cracking; (5) his belief that PVDF is a viable alternative design; and (6) Ethicon's knowledge, intentions, or beliefs with respect to PVDF. (Mem. of Law in Supp. of Defs.' Mot. to Exclude or, Alternatively, to Limit the Ops. & Test. of Dr. Howard Jordi, Ph.D. ("Defs.' Mem. re: Jordi") [Docket 119], at 2). For the reasons discussed below, the defendants' motion with respect to Dr. Jordi is **DENIED as moot in part** and **DENIED in part**.

1. **Degradation Generally**

Throughout their *Daubert* briefing, the defendants contend that expert opinions on degradation are not helpful to the jury because the plaintiff cannot prove specific causation and because no expert can say that degradation is clinically significant. As I have previously held in these MDLs, general causation opinions are helpful to the jury and fit the facts of this case

regardless of whether the plaintiff may ultimately fail to carry her burden to show that she was harmed by the Prolift implant. Accordingly, I reject the defendants' argument with regard to the relevancy of degradation in the context of all expert witnesses.

2. Qualifications

Next, the defendants contend that Dr. Jordi is unqualified to opine on the clinical or mechanical effects of degradation. (Defs.' Mem. re: Jordi [Docket 119], at 7). The plaintiff concedes that "Dr. Jordi will not offer medical opinions[.]" (Pl.'s Resp. re: Jordi [Docket 157], at 3). Therefore, the defendants' motion with regard to the clinical effects of degradation is **DENIED as moot.**

The defendants also contend that Dr. Jordi is unqualified to opine on the mechanical effects of degradation because he is "not a mesh design specialist or biomechanical engineer." (Defs.' Mem. re: Jordi [Docket 119], at 7). Dr. Jordi has an undergraduate degree in Chemistry and a Ph.D. in biochemistry. (Jordi Report [Docket 135] at 1). He is the founder of Jordi Labs, which specializes in the analysis of polymers, like polypropylene. (*Id.*). In his expert report, Dr. Jordi states that he has been analyzing polypropylene for over 25 years. (*Id.*). Furthermore, in *Lewis*, the court allowed Dr. Jordi to offer expert opinions about polypropylene degradation without objection. (*See* Lewis Trial Tr. [Docket 157-1], at 19). Accordingly, I **FIND** that Dr. Jordi is qualified to opine on the mechanical effects of degradation.

The defendants also appear to make a reliability argument regarding Dr. Jordi's degradation opinions. However, in his expert report, Dr. Jordi describes numerous tests he performed on Ms. Bellew's mesh explant, and subsequently concludes that based on his review of the scientific literature and his knowledge, training, and experience in polymer science, "this level of degradation will have a *strong impact* on fiber mechanical properties." (Jordi Report [Docket 135], at 22). Accordingly, I **FIND** Dr. Jordi's opinions regarding the mechanical effects

of degradation sufficiently reliable under *Daubert*.

3. Non-party Explants

Next, the defendants argue that the court should exclude any opinions or evidence concerning explants removed from non-parties. (Defs.' Mem. re: Jordi [Docket 119], at 9). The plaintiff concedes that "Dr. Jordi will not offer . . . opinions concerning his review of other explants." (Pl.'s Resp. re: Jordi [Docket 157], at 3). Therefore, the defendants' motion with regard to non-party explants is **DENIED as moot**.

4. Surface Degradation

Next, the defendants contend that if Dr. Jordi is permitted to opine on the degradation of Ms. Bellew's mesh, these opinions should be limited to surface degradation, given that Dr. Jordi has not observed any degradation of the inner layer of Ms. Bellew's mesh. (Defs.' Mem. re: Jordi [Docket 119], at 10). As discussed more fully above, Dr. Jordi is qualified to opine on degradation, and his opinions are reliable. Nowhere in his expert report does Dr. Jordi specifically opine that the "inner layer" of Ms. Bellew's mesh degraded. If the defendants are concerned that the jury will incorrectly infer that Dr. Jordi's use of the term "degradation" generally includes the inner layer of Ms. Bellew's mesh, they are free to clarify that issue at trial. Accordingly, the defendants' motion with regard to surface degradation is **DENIED**.

5. Environmental Stress Cracking

Next, the defendants argue that Dr. Jordi's opinions on environmental stress cracking ("ESC") are unreliable, unhelpful, and inadmissible. (Defs.' Mem. re: Jordi [Docket 119], at 11). The defendants claim that Dr. Jordi is unable to offer an opinion on ESC to a reasonable degree of scientific certainty. I disagree. The defendants attempt to conflate Dr. Jordi's opinion that Ms. Bellew's Prolene mesh was *susceptible* to ESC with the opinion that the mesh actually underwent ESC. Dr. Jordi specifically states that he cannot definitively determine whether

oxidation or ESC caused the cracking. (*See* Jordi Dep. [Docket 118-3], at 96-97). However, in both his expert report and deposition, he opines, to a reasonable degree of scientific certainty, that Ms. Bellew's mesh was *susceptible* to ESC. (Jordi Report [Docket 135], at 166; Jordi Dep. [Docket 118-3], at 98). Dr. Jordi's opinion is based on his examination of Ms. Bellew's mesh and supported by peer-reviewed literature. Accordingly, the defendant's motion with regard to ESC is **DENIED**.

6. PVDF as Alternative Polymer

Next, the defendants contend that Dr. Jordi's opinions regarding PVDF as an alternative polymer are unreliable because he fails to cite any peer-reviewed studies establishing that PVDF is safer and more effective than Prolene. The defendants' emphasis on safety and efficacy relates back to their original argument regarding the relevancy of degradation, which I rejected above. Disregarding this argument, the defendants are incorrect in their assertion that Dr. Jordi fails to cite any peer-reviewed studies in support of his opinion. In his expert report, when discussing PVDF, Dr. Jordi cites the Celine Mary study and Ethicon's dog study. (*See* Jordi Report [Docket 135], at 7, 9). Furthermore, I previously allowed Dr. Jordi to testify that "PVDF is much more resistant to degradation than polypropylene, and that polypropylene is more susceptible to degradation." (Lewis Trial Tr. [Docket 157-1], at 41). Accordingly, the defendants' motion with regard to PVDF is **DENIED**.

7. Ethicon's Knowledge, Intentions, Beliefs

Lastly, the defendants ask the court to exclude Dr. Jordi's opinions about Ethicon's knowledge, intentions, or beliefs regarding PVDF. (Defs.' Mem. re: Jordi [Docket 119], at 14). The plaintiff concedes that "Dr. Jordi will not offer opinions concerning Ethicon's state of mind or corporate conduct." (Pl.'s Resp. re: Jordi [Docket 157], at 14). Therefore, the defendants' motion with regard to Ethicon's knowledge, intentions, and beliefs is **DENIED as moot**.

B. Motion to Exclude the Opinions & Testimony of Dr. Thomas Mühl

The defendants seek to exclude the opinions and testimony of Dr. –Ing. Thomas Mühl. Dr. Mühl holds a Ph.D. in electrical engineering and, along with Dr. Uwe Klinge, developed a concept called "effective porosity," which is defined as a percentage of the area of mesh that has a pore size of greater than one millimeter in all directions. (Mühl Report [Docket 107-1], at 2). The effective porosity threshold is based on the theory that pores should be at least one millimeter in all directions in order to (1) prevent fibrotic bridging and (2) permit tissue ingrowth. (*See id.*). Utilizing his effective porosity theory, Dr. Mühl determined that Ethicon's Prolift has an effective porosity of 26.0%. (*Id.* at 26).

I have previously reviewed the reliability of Dr. Mühl's effective porosity theory under *Daubert*. *See Lewis, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-4301, 2014 WL 186872, at *3-5 (S.D. W. Va. Jan. 15, 2014). While the parties in this case have not relied on precisely the same arguments, my reasoning and conclusions from *Lewis* still govern. Furthermore, to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. In *Lewis*, I ruled as follows:

> First, Ethicon argues that Dr. Mühl's opinions are not reliable because they are not generally accepted. The concept of effective porosity is apparently adopted only in articles authored by Drs. Mühl and Klinge, and it is used only by a single manufacturer, FEG Textiltechnik ("FEG"), a company affiliated with Drs. Mühl and Klinge. But general acceptance is merely one factor a court should consider in determining admissibility of expert testimony. A court should consider numerous factors, none of which is dispositive, in determining whether an expert's methods pass muster under *Daubert*. *See United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003). In addition to general acceptance, a court should consider whether an expert's theories have been "subjected to peer review and publication." *Daubert*, 509 U.S. at 593. Dr. Mühl's effective porosity theories are published in several peer-reviewed articles. (*See, e.g.*, Mühl Dep. [Docket 161-6], at 244:14-245:19; Klinge Report [Docket 132-1], at 18 (citing Mühl T. et al., *New Objective Measurement to Characterize the Porosity of Textile Implants*, J. Biomed. Mater. Res. Part B: Applied Biomaterials 176-183 (2007)), *id.* (citing J. Otto et al., *Elongation of Textile Pelvic Floor Implants Under Load is Related to Complete*

Loss of Effective Porosity, thereby Favoring Incorporation of Scar Plates, J. Biomed. Mater. Res. Part A 1-6 (2013))).

Second, Ethicon argues that these opinions are unreliable because Drs. Mühl and Klinge have contradicted themselves in the past by stating that pores measuring less than one millimeter can be effective. (*See* Defs.' Mem. re: Mühl [Docket 138], at 8). An expert's contradictory prior statements may indicate that the expert's methods are unreliable, but that is not necessarily dispositive. The relevant inquiry is whether the proffered opinions are sufficiently reliable under *Daubert*. Dr. Klinge explained in his deposition that they adopted the one millimeter parameters in reliance on the Conze study and his research with Dr. Bernd Klosterhalfen. (*See* Klinge Dep. [Docket 161-10], at 376:14-377:16; 663:13-664:3). With support from a peer-reviewed publication, I am not convinced that opinions regarding the one millimeter parameters are unreliable.

Third, Ethicon suggests that the methods for testing effective porosity are unreliable because they were developed for FEG, a direct competitor of Ethicon. But as Ethicon admits, "a proffered expert witness's financial interest often goes to the weight rather than the admissibility of testimony." (Defs.' Mem. re: Mühl [Docket 138], at 7). "[I]t is well-settled that an expert witness's bias goes to the weight, not the admissibility of the testimony, and should be brought out on cross-examination." *Grant Thornton, LLP v. F.D.I.C.*, 297 F. Supp. 2d 880, 884 (S.D.W. Va. 2004) (Faber, J.). Ethicon is free to highlight this conflict of interest on cross-examination.

Fourth, Ethicon contends that even if I permit Dr. Mühl to testify about his effective porosity opinions, I should still prohibit his opinions regarding "effective porosity under strain" because they fail to take into account the wide range of physical forces exerted on implanted mesh. (*See* Defs.' Mem. re: Mühl [Docket 138], at 9-11). In order to test the TVT mesh's effective porosity while subjected to the mechanical forces of the human body, Dr. Mühl applied uniaxial forces (pulling from one side) between a range of 102 grams and 1,000 grams to the mesh. Ethicon argues that, in the human body, meshes are subject to forces from multiple directions simultaneously and that the actual forces to which urethral slings are subjected are estimated to be less than 50 grams. (*See* Defs.' Mem. re: Mühl [Docket 138], at 10). The plaintiffs retort that Ethicon used the same uniaxial loads to test its own products. (*See, e.g.*, Mühl Report [Docket 137-1], at 6 ("Ethicon's manner of applying uniaxial loads to Ethicon mesh to determine the behavior of mesh is strikingly similar to our test method.")). Further, Dr. Klinge explained that because slings are only one centimeter wide, any force attempting to make a sling wider will be very small (*see* Klinge Dep. [Docket 161-10], at 483:7-9), and the downward forces exerted on the sling by the pelvic floor will create a largely uniaxial strain (*id.* at 482:22-438:5). Finally, Dr. Mühl's expert report cites a published study employing similar uniaxial tensile testing methods to analyze Ethicon slings. (*See* Mühl Report [Docket 137-1], at 6).

> Lastly, Ethicon argues that Dr. Mühl impermissibly relied on unreliable medical opinions of Dr. Klinge, but Ethicon does not point to any specific statements or opinions that it challenges. (*See* Defs.' Mem. re: Mühl [Docket 138], at 11). In any event, I address Ethicon's challenges to Dr. Klinge below.
>
> Ethicon's arguments do not convince me that Dr. Mühl's opinions regarding effective porosity are unreliable. I therefore **FIND** that Dr. Mühl's opinions regarding effective porosity are not excluded.

Lewis, 2014 WL 186872, at *3-5. Therefore, I **ADOPT** my prior ruling on Dr. Mühl, as stated in *Lewis*, and **FIND** that his opinions regarding effective porosity are sufficiently reliable under *Daubert*.

C. Motion to Limit the Testimony of Dr. Uwe Klinge

The defendants seek to limit the opinions of Dr. Uwe Klinge. Dr. Klinge is a former hernia surgeon with extensive research experience in the area of biomaterials and surgical mesh. The plaintiff offers Dr. Klinge to opine on the biomaterials used in Ethicon's Prolift and how certain design deficiencies have resulted in numerous complications. Ethicon moves to preclude "Dr. Klinge from offering opinions at trial related to the following topics: (1) Ethicon's alleged knowledge, bad acts, state of mind, and corporate conduct; (2) mesh degradation, fraying, and particle loss, (3) effective porosity; and (4) alternative design." (Defs.' Mot. to Limit the Test. of Prof. Dr. Med. Uwe Klinge [Docket 101], at 1). For the reasons discussed below, the defendants' motion is **DENIED as moot, DENIED in part**, and **GRANTED in part**.

1. State of Mind

First, the defendants argue that Dr. Klinge's "narrative summary of Ethicon documents and Depositions and his opinions concerning Ethicon's knowledge, state of mind, and corporate conduct should be excluded." (Defs.' Mem. in Supp. of Mot. to Limit. The Test. of Prof. Dr. Med. Uwe Klinge ("Defs.' Mem. re: Klinge") [Docket 102], at 2). However, the plaintiff "has no intention of eliciting testimony from Dr. Klinge that would characterize Ethicon's state of mind

or corporate intent." (Pl.'s Resp. in Opp. to Defs.' Mot. to Limit the Test. of Prof. Dr. Med. Uwe Klinge ("Pl.'s Resp. re: Klinge") [Docket 149], at 5). Therefore, the defendants' motion with regard to Ethicon's state of mind is **DENIED as moot.**

2. Mesh Degradation, Fraying, & Particle Loss

Next, the defendants contend that "the [c]ourt should further exclude Dr. Klinge's general opinion that the Prolift is defective because its mesh degrades in vivo and is subject to fraying and particle loss" because he cannot explain the clinical significance of these alleged conditions. (Defs.' Mem. re: Klinge [Docket 102], at 3). I disagree. In his expert report, Dr. Klinge ascribes particular complications to degradation, fraying, and particle loss. For instance, when discussing degradation, he states "that oxidation of mesh . . . . leads to embrittlement of the material, impaired tissue mobility and eventually chronic pain." (Klinge Report [Docket 101-2], at 18). In his discussion of fraying and particle loss, Dr. Klinge also states that "particulates scattered throughout the pelvic tissue will create an inflammatory response of some magnitude; will increase the overall foreign body reaction and inflammatory response; will increase the amount of the fibrotic reaction; and will run the risk of migrating into other parts of the body." (*Id.* at 21). Furthermore, throughout both of these sections of his expert report, Dr. Klinge supports his opinions, at least in part, by citing to peer-reviewed, published literature. (*See* Klinge Report [Docket 101-2], at 18-21 (citing studies by Costello, Clave, and Moalli, to name a few)). Therefore, consistent with my decision in *Lewis*, I **FIND** that Dr. Klinge is permitted to testify generally about polypropylene's tendency to degrade, fray, or lose particles and its effect on the human body. *See* 2014 WL 186872, at *7.

3. Effective Porosity

Next, the defendants argue that "the court should exclude Dr. Klinge's opinions regarding effective porosity" by "incorporate[ing] by reference their motion to exclude Dr. Mühl and the

memorandum supporting the same." (Defs.' Mem. re: Klinge [Docket 102], at 6). Dr. Klinge's opinions regarding effective porosity are based on Dr. Mühl's testing, examined above. (*See* Klinge Report [Docket 101-2], at 15-16 ("In connection with this litigation, Prof. Mühl performed testing on Ethicon's surgical mesh product [Prolift/TVT Products] using the same protocol as we used in our study in 2007 and as reported again in 2013.")). Therefore, for the reasons discussed in relation to Dr. Mühl, and consistent with my decision in *Lewis*, I **FIND** that Dr. Klinge is permitted to testify about effective porosity and pore deformation. *See* 2014 WL 186872, at *7.

4. Alternative Design

Lastly, the defendants contend that "Dr. Klinge should be precluded from testifying about feasible alternative designs" because his expert report does not explain the basis for his opinion that PVDF is a safer design. (Defs.' Mem. re: Klinge [Docket 101], at 6). The plaintiff argues that I previously allowed Dr. Klinge to opine on alternative design in *Lewis* and that he references the same publications in his *Bellew* report that he referenced in his *Lewis* report. The plaintiff is mistaken. In *Lewis*, Dr. Klinge cited multiple peer-reviewed studies to support his opinions on Dynamesh, including the Klink and Silva studies. *See* 2014 WL 186872, at *7. Here, Dr. Klinge simply states that "[t]he PVDF product is a safer design for all of the reasons stated above," referencing his discussion of effective porosity. (Klinge Report [Docket 101-1], at 16). In the section of his report specifically addressing alternative design, Dr. Klinge fails to cite *any* peer-reviewed studies. (*See id.* at 24-27). Dr. Klinge's report provides no indication that his alternative design opinions are based on anything other than his and Dr. Mühl's effective porosity testing and internal Ethicon documents, which are not sufficiently reliable scientific bases under *Daubert*. (*See* Defs.' Reply in Supp. of Mot. to Limit the Test. of Prof. Dr. Med. Uwe Klinge [Docket 162], at 3-4 ("Nowhere does Dr. Klinge report that this [effective porosity]

testing was conducted on a mesh made of PVDF, nor does Dr. Klinge state elsewhere in his report that PVDF mesh would perform differently under similar testing.")). Accordingly, I **FIND** that Dr. Klinge's alternative design opinions should be **EXCLUDED.**

D. Motion to Exclude Certain Opinions of Daniel S. Elliott, M.D.

The defendants seek to exclude certain opinions of Dr. Daniel S. Elliott. Dr. Elliott is an associate professor of urology, section of Female Urology and Reconstructive Surgery, at Mayo Clinic Graduate School of Medicine in Rochester, Minnesota who has treated hundreds of patients with mesh-related complications. (Elliott Report [Docket 116-1], at 2). In preparation for this litigation, Dr. Elliott consulted approximately 300 publications, reviewed Ms. Bellew's medical records, and performed an independent medical examination of Ms. Bellew. (Pl.'s Resp. to Defs.' Mot. to Exclude Certain Ops. Of Daniel S. Elliott, M.D. ("Pl.'s Resp. re: Elliott") [Docket 150], at 2). In his expert report, Dr. Elliott concludes that (1) the Prolift has a lack of clinical benefit; (2) the Prolift causes serious and potentially permanent injuries due to complications associated with its implantation; (3) Ethicon failed to completely disclose to physicians and patients the risks of using the Prolift; and (4) Ethicon breached its duty of reasonable care. (*See* Elliott Report [Docket 116-1], at 3-5). The defendants move to exclude the following opinions offered by Dr. Elliott: (1) the defendants' knowledge, state of mind and alleged bad acts; (2) legal opinions; (3) product marketing; (4) regulatory opinions; (5) matters that do not fit the facts of this case; (6) supposed underreporting of complications; (7) other matters for which Dr. Elliott lacks support; (8) degradation; (9) patents; (10); physician training; (11) communications between Plaintiff and her treating physicians; (12) Ethicon's discontinuation of the Prolift; (1) and opinions not set forth in his report. (Defs.' Mot. to Exclude Certain Ops. of Daniel S. Elliott, M.D. [Docket 116], at 1). I agree with the plaintiff that the

defendants have taken a "scatter-shot" approach, which would be better suited for a motion *in limine*. (Pl.'s Resp. re: Elliott [Docket 150], at 1). Nevertheless, I proceed to review each objection in turn.

1. State of Mind

The defendants point out various instances where Dr. Elliott opines on Ethicon's knowledge or state of mind. (*See* Defs.' Mem. re: Elliott [Docket 117], at 2-3). The plaintiff appears to agree that Dr. Elliott may not opine on Ethicon's alleged knowledge or state of mind, but argues that Dr. Elliott's statements regarding what Ethicon did or did not do "go beyond opinions about Ethicon's state of mind or corporate conduct." (Pl.'s Resp. re: Elliott [Docket 150], at 5 (internal quotation marks omitted)). I disagree. Whether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct. (*See* Elliott Report [Docket 116-1] at 42, 44). As I previously discussed, Ethicon's state of mind, knowledge, or corporate conduct are not appropriate subjects of expert testimony because they are not helpful to the jury. *See* Fed. R. Evid. 702. Therefore, these opinions are **EXCLUDED.**

2. Legal Opinions

The defendants argue that Dr. Elliott should be precluded from testifying as to what a "reasonably prudent medical device manufacturer would or would not do." (Defs.' Mem. re: Elliott [Docket 117], at 3). The plaintiff "agrees that Dr. Elliott will not use the phrases 'reasonably prudent medical device manufacturer' or 'duty of reasonable care.'" Therefore, the defendants' motion with regard to legal opinions is **DENIED as moot.**

3. Marketing Opinions

The defendants contend that Dr. Elliott is unqualified to offer opinions on Ethicon's marketing of the Prolift. (*Id.* at 4). The plaintiff concedes that Dr. Elliott is not an expert in

marketing and "true marketing opinions should be excluded." Nevertheless, I agree with the plaintiff that Dr. Elliott's statement that "the Prolift System should have never been marketed to surgeons or patients in the first place," addresses the Prolift's safety, and not the defendants' marketing techniques. (Elliott Report [Docket 116-1], at 3). Therefore, the defendants' motion with regard to marketing opinions is **DENIED as moot in part** and **DENIED in part**. To the extent that the defendants have further objections, they are free to raise them at trial.

4. Regulatory Opinions

The defendants ask this court to preclude Dr. Elliott from providing regulatory opinions because he has conceded that he is not a regulatory expert. (Defs.' Mem. re: Elliott [Docket 117], at 5). The plaintiff indicates that she "does not intend to raise any FDA clearance issues" (Pl.'s Resp. re: Elliott [Docket 150], at 6). Therefore, the defendants' motion with regard to regulatory opinions is **DENIED as moot.**

5. Irrelevant Opinions

a. Alleged Complications the Plaintiff Never Developed, Including Mesh Erosion & Performance of a Cystoscopy

First, the defendants argue that Dr. Elliott's opinions on conditions the plaintiff never suffered should be excluded because they are irrelevant, including "adhesions, vaginal retraction and shortening, fistula formation, chronic infection, chronic wound healing issues, organ erosion, bladder perforation, rectal perforation, vascular injury, injury to the pudendal nerve, nerve entrapment, chronic inflammatory process, and [ ]sarcomas." (Def.'s Mem. re: Elliott [Docket 117], at 6 (internal quotation marks omitted)). The defendants also ask the court to exclude Dr. Elliott's opinions on mesh erosion—because the plaintiff's mesh did not erode—and cystoscopies—because the plaintiff did not require or receive one. (*Id.* at 7). The plaintiff claims that all ways in which a product might injure a particular plaintiff are relevant under Arizona

law; and furthermore, the plaintiff did in fact suffer some of the complications the defendants wish to exclude. (Pl.'s Resp. re: Elliott [Docket 150], at 8-9).

Evidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value. First, in regard to the plaintiff's strict liability claim, I disagree with the plaintiff's reading of *Golonka v. General Motors Corp.*, 65 P.3d 956 (Ariz. 2003). The plaintiff asserts that "likelihood of injury," one of the factors assessed under the risk/benefit analysis, refers to the likelihood of *any* injury. However, a strict liability claim requires "the defective condition proximately cause *the plaintiff's* injury[.]" *Anderson v. Nissei ASB Mach. Co.*, 3 P.3d 1088, 1092 (Ariz. 1999) (emphasis added). Reading the elements of the prima facie case and the risk/benefit factors together, the pertinent injury is clearly that which the plaintiff actually suffered. Second, although the plaintiff's argument that *any* warning is relevant to proximate cause based on Dr. Dehasse's testimony has some merit, elaborating on injuries that the plaintiff did not incur risks "confusing the issues [and] misleading the jury." Fed. R. Evid. 403. Therefore, the defendants' motion on this issue is **GRANTED** and Dr. Elliott's opinions on complications the plaintiff never developed are **EXCLUDED**. To the extent that the parties disagree as to what complications the plaintiff suffered, these objections are better suited for trial.

b. Mesh Procedures Not Administered to the Plaintiff

Next, the defendants contend that Dr. Elliott's opinions about mesh procedures that the plaintiff did not undergo do not fit the facts of the case. (Defs.' Mem. re: Elliott [Docket 117], at 8). The plaintiff "agrees that Dr. Elliott will not address the posterior and apical Prolift procedures." (Pl.'s Resp. re: Elliott [Docket 150], at 7). Therefore, the defendants' motion with regard to mesh procedures not administered to the plaintiff is **DENIED as moot.**

c. Prolift Appropriateness for Certain Populations

Lastly, the defendants argue that Dr. Elliott's opinions on Ethicon's marketing of the Prolift to overweight and elderly patients are irrelevant, given that the plaintiff is neither overweight nor elderly. (Defs.' Mem. re: Elliott [Docket 117], at 8). Again, the plaintiff "agrees that Dr. Elliott will not talk about whether the Prolift is appropriate for overweight and elderly patients." (Pl.'s Resp. re: Elliott [Docket 150], at 7 (internal quotation marks omitted)). Therefore, the defendants' motion with regard to the Prolift's appropriateness for certain populations is **DENIED as moot.**

6. Underreporting of Complications

The defendants argue that Dr. Elliott's opinions on the underreporting of complications should be excluded because they are conclusory and unreliable. (Defs.' Mem. re: Elliott [Docket 117], at 8). Dr. Elliott only cites one peer-reviewed article that the defendants argue examines drugs, not medical devices. (*Id.* at 9). However, the plaintiff points out that although the Kessler article focuses on drugs, the author also discusses "device-induced disease." (Pl.'s Resp. re: Elliott [Docket 150], at 11). Dr. Elliott's decision to rely on the Kessler article indicates his opinions are not conclusory and that he utilized a reliable methodology. Whether the defendants disagree with Dr. Elliott's ultimate conclusion that the Kessler article supports his opinion with regard to medical devices is not a sufficient basis to object under *Daubert*. Additionally, the defendants' concern with the lack of additional support goes to the weight of Dr. Elliott's testimony and can be adequately addressed on cross-examination. Accordingly, the defendants' motion with regard to underreporting of complications is **DENIED.**

7. Other Matters Lacking Support

In its seventh point, the defendants list ten page references where Dr. Elliott allegedly

fails to support his opinions with "citations to medical literature or other information." (Defs.' Mem. re: Elliott [Docket 117], at 9-10). The defendants provide no further explanation as to why these portions of Dr. Elliott's report should be excluded under *Daubert*. Without more specific information, I am unable to review the merits of such a motion. One instance with which the defendants take specific issue is Dr. Elliott's opinion on anatomic recurrence rates. Although Dr. Elliott fails to cite any scientific literature in his discussion of this topic in his report, when asked about anatomic recurrence rates during his deposition, Dr. Elliott indicates he relied on three different papers in coming to this conclusion. (Elliott Dep. [Docket 116-2], at 113 (naming Chmielewski, Walters, and Weber)). Dr. Elliott's response is sufficient to establish reliability under *Daubert*. Therefore, the defendants' motion with regard to anatomic recurrence rates is **DENIED.**

8. Degradation

The defendants argue that Dr. Elliott is unqualified to opine on mesh degradation and that his opinions are "unconnected to any reliable methodology." (Defs.' Mem. re: Elliott [Docket 117], at 11-15). With regard to his qualifications, the defendants contend that Dr. Elliott has no experience in the field of polymer science and has not shown that he possesses any specialized knowledge observing mesh degradation in his practice. (*Id.* at 13).

An expert may be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all the details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). Dr. Elliott has personally treated patients with Prolift mesh complications "too numerous to count." (Elliott Dep. [Docket 116-2], at 178). He has published nearly 60 peer-reviewed articles and given over 100 lectures pertaining

to POP. (Elliott Report [Docket 116-1], at 2). Additionally, he has published two scientific manuscripts dealing specifically with polypropylene mesh. (*Id.*). According to Dr. Elliott, his "practice has become increasingly dedicated to treating a whole host of life-altering complications associated with the use of both SUI and POP meshes, including meshes made by Ethicon." (*Id.*). Therefore, I **FIND** that Dr. Elliott is qualified to offer opinions on mesh degradation.

With regard to his methodology, Dr. Elliott bases his opinions on both his clinical experience, as well as his extensive review of the scientific literature and internal Ethicon documents. Specifically, in the section of his report discussing mesh degradation, Dr. Elliott cites numerous peer-reviewed studies and articles to support his assertions. (*See* Elliott Report [Docket 116-1], at 34-35 (citing Costello and Clave in the text, to name a few)). Accordingly, I **FIND** that Dr. Elliott may testify regarding mesh degradation.

9. Patents

The defendants ask the court to preclude Dr. Elliott from expressing opinions about Ethicon's patents because he is not a patent expert. (Defs.' Mem. re: Elliott [Docket 117], at 14). The plaintiff indicates that Dr. Elliott has not and will not offer expert opinions on Ethicon's patents. Therefore, the defendants' motion with regard to patents is **DENIED as moot.**

10. Physician Training

The defendants seek to preclude Dr. Elliott from testifying about physician training because his opinions are unreliable and not helpful to the jury. (*Id.* at 15). However, in their Memorandum in Support, the defendants only take issue with one particular statement by Dr. Elliott: "Ethicon representatives pushed the envelope on training." (*Id.* (quoting Elliott Report [Docket 116-1], at 43-44)). As indicated in the footnotes, the phrase "pushed the envelope" is

taken directly from an email written by an Ethicon district manager. (*See* Elliott Report [Docket 116-1], at n.285). Furthermore, although the section as a whole consists of a review of corporate documents, Dr. Elliott comments on the quality of training by pointing out where Ethicon failed to inform physicians of certain risks and complications, as well as why such information is critical. (*See, e.g.*, Elliott Report [Docket 116-1], at 48 ("Mesh exposure and bladder injury are common[ ]complications, yet there is inadequate guidance in the Surgical Guide on managing these complications. An absence of a description and guidance in the management of these complications minimizes the frequency and magnitude of these complications to a surgeon.")). In Arizona, under the risk/benefit analysis, one of the factors to be considered is "the avoidability of injury by care in use of the product (including the effect of instructions or warnings)[.]" *Golonka*, 65 P.3d at 962 n.2. I agree with the plaintiff that "[t]his standard places into issue whether Ethicon provided sufficient guidance to surgeons through the Prolift [IFU], the Surgical Guide, and any training programs offered." Accordingly, the defendants' motion with regard to physician training is **DENIED**.

11. Communications Between the Plaintiff and Her Treating Physicians

The defendants argue that Dr. Elliott's summary of the discussion between the plaintiff and her treating physician, Dr. Dehasse, should be excluded because "Dr. Elliott has no specialized knowledge enabling him to render *expert opinions* about what Dr. Dehasse did or did not discuss with Plaintiff." (Defs.' Mem. re: Elliott [Docket 117], at 15 (emphasis added)). The defendants' contention is misplaced, however, because Dr. Elliott is not offering an expert opinion in this section of his report. He is merely summarizing the factual record, which does not require the use of "scientific, technical, or other specialized knowledge." Fed. R. Evid. 702. Therefore, I will not address the admissibility of this testimony here and **RESERVE** ruling for

trial.

12. Withdrawal of Prolift

The defendants contend that Dr. Elliott's discussion of Ethicon's decision to withdraw the Prolift from the market is irrelevant because it took place after the plaintiff's implant procedure, and that Dr. Elliott is not qualified to render an opinion on Ethicon's decision. I agree with the plaintiff that "[u]ltimately, the issue of whether Defendants' withdrawal of [the] Prolift from the market is relevant to this case should be decided based on [future] briefing." (Pl.'s Resp. re: Elliott [Docket 150], at 17). Regardless, as discussed more fully above, Ethicon's state of mind—its reasoning behind the decision to withdraw the Prolift—is not an appropriate subject for expert testimony. Accordingly, the defendants' motion on this issue is **GRANTED** and Dr. Elliott's opinions on why Ethicon withdrew the Prolift are **EXCLUDED**.

13. Opinions Not Set Forth in Expert Report

Finally, the defendants seek to exclude opinions not set forth in Dr. Elliott's report as required by Federal Rule of Civil Procedure 26(a)(2)(B)(i). (Defs.' Mem. re: Elliott [Docket 117], at 16). The plaintiff concedes that there was no discussion of ischemia in Dr. Elliott's report, and that he will not opine on that subject at trial. (Pl.'s Resp. re: Elliott [Docket 150], at 17). Therefore, the defendants' motion with regard to ischemia is **DENIED as moot**. Objections to the following opinions remain: (1) granulation; (2) nerve injury; and (3) future surgeries.

a. Granulation

In his expert report, Dr. Elliott states that Dr. Dehasse and Dr. Joseph noted that Ms. Bellew experienced tissue granulation, in addition to a variety of other complications. (*See* Elliott Report [Docket 116-1], at 60-61). Dr. Elliott subsequently concludes "[t]o a reasonable degree of medical certainty, *each of* the permanent complications, injuries, and the consequences

thereof, as documented herein and in the medical records, was caused by all of the defects and problems with the Prolift discussed throughout this report." (*Id.* at 64 (emphasis added)). This conclusion clearly includes granulation, which was discussed with regard to Ms. Bellew's medical records. Accordingly, the defendants' motion with regard to granulation is **DENIED**.

b. Nerve Injury

Throughout his expert report, Dr. Elliott discusses nerve injury as "a critically important . . . condition following Prolift POP repair." (Elliott Report [Docket 116-1], at 27). However, with regard to his examination and diagnosis of Ms. Bellew, Dr. Elliott fails to specifically mention nerve injury. In his deposition, Dr. Elliott states that Ms. Bellew "possibly" had nerve injury based on his discussion of her pelvic muscle spasms in his report. Under Rule 26, expert reports must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Accordingly, the defendants' motion with regard to nerve injury is **GRANTED**, and Dr. Elliott's opinions on this issue are **EXCLUDED**.

c. Future Surgeries

Finally, Dr. Elliott clearly states that Ms. Bellew "will continue to . . . need future medical care," which could include future surgeries. Dr. Elliott indicates that he holds this opinion to a reasonable degree of medical certainty based on his review of Ms. Bellew's medical records, his examination of Ms. Bellew, and his knowledge and opinions on the Prolift as discussed throughout his report. Accordingly, I **FIND** that Dr. Elliott addressed future surgeries in his expert report, and that his opinions are sufficiently reliable under *Daubert*.

E. Motion to Exclude the Testimony of Dr. Vladimir Iakovlev, M.D.

The defendants seek to exclude the opinions of Dr. Vladimir Iakovlev in their entirety. Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of

Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. (Iakovlev Report [Docket 121-1], at 1). In his expert report, Dr. Iakovlev describes a study he participated in with Dr. Robert Bendavid beginning in 2012 to "analyze explanted meshes and . . . provide a correlation between pathological findings and clinical symptoms." (*Id.*). Based on this study, as well as his background in pathology, Dr. Iakovlev concludes "that women implanted with pelvic mesh devices are at an increased risk of suffering chronic and debilitating pelvic pain and dyspareunia as a result of the higher innervation of that anatomical region of the body compared to the anterior abdominal wall." (*Id.* at 2).

The defendants make the following arguments regarding the admissibility of Dr. Iakovlev's opinions under *Daubert*: (1) Dr. Iakovlev's opinions regarding potential complications are unreliable and irrelevant; (2) Dr. Iakovlev is unqualified to opine on degradation and his opinions are unreliable and irrelevant; (3) Dr. Iakovlev's nerve density analysis is unreliable; (4) Dr. Iakovlev's opinions regarding mesh deformation and folding are unreliable and speculative; (5) Dr. Iakovlev's opinions regarding Ms. Bellew's urinary symptoms are speculative; (6) Dr. Iakovlev's proposed testimony significantly exceeds his expertise; and (7) Dr. Iakovlev's opinion about Ms. Bellew's post-explant condition is speculative. (Defs.' Mem. of Law in Supp. of Mot. to Exclude the Ops. & Test. of Dr. Vladimir Iakovlev (Defs.' Mem. re: Iakovlev [Docket 122]). The plaintiff "agrees not to question Dr. Iakovlev on the mesh design and mesh knitting, about the other 130 surgical mesh explants he has analyzed prior to this case, the Bark Thickness Correlation Chart that uses data from other explants, or Ms. Bellew's future pain as a result of the Prolift implant." (Pl.'s Resp. in Opp. to Defs.' Mot. & Mem. of Law to Exclude the Ops. & Test. of Vladimir Iakovlev, M.D. ("Pl.'s Resp. re: Iakovlev [Docket 156], at 2). Accordingly, to the extent that the defendants' motion

relates to one of the areas of testimony conceded by the plaintiff, it is **DENIED as moot.**

1. Degradation

First, the defendants contend that the court should exclude Dr. Iakovlev's opinions regarding degradation because Dr. Iakovlev is unqualified to testify as to the chemical composition of Ms. Bellew's explanted mesh and his opinions are unreliable. (Defs.' Mem. re: Iakovlev [Docket 122], at 5-13). I have previously reviewed Dr. Iakovlev's qualifications and the reliability of his degradation opinions under *Daubert*. *See Eghnayem, et al. v. Boston Scientific Corp.*, No. 2:13-cv-07965, 2014 WL 5461991, at *46 (S.D. W. Va. Oct. 27, 2014). While the parties in this case have not relied on precisely the same arguments, my reasoning and conclusions from *Eghnayem* still govern. In *Eghnayem*, I ruled as follows:

> **a. Qualifications**
>
> A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information. *Edwards*, 2014 WL 3361923, at *24 (citation omitted). In his expert report, Dr. Iakovlev states that his "professional activities include diagnostic examination of specimens surgically removed from human patients" where his "annual practice volume amounts to 5000 cases." (Iakovlev Report [Docket 105-1], at 2). Dr. Iakovlev describes himself as an "academic physician" who "pursue[s] research endeavors and teach[es] medical students and residents." (*Id.*). BSC does not question Dr. Iakovlev's pathology credentials; rather, it only argues that as a pathologist, he is unqualified to render these opinions. However, throughout these MDLs, I have allowed numerous pathologists to testify regarding the properties of polypropylene mesh. *See, e.g., Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *19–20 (S.D. W. Va. Sept. 29, 2014) (discussing Dr. Richard W. Trepeta); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) (discussing Dr. Bernd Klosterhalfen). In fact, in *Edwards*, I determined that Dr. Iakovlev was qualified to render opinions specific to that plaintiff's mesh based on his experience as a pathologist. *See Edwards*, 2014 WL 3361923, at *24–25. Therefore, I **FIND** that Dr. Iakovlev is qualified to offer specific causation opinions regarding Ms. Eghnayem based on his pathological examination of her mesh explants.

Eghnayem, 2014 WL 5461991, at *46. Therefore, I **ADOPT** my prior ruling on Dr. Iakovlev's qualifications, as stated in *Eghnayem*, and **FIND** that he is qualified to opine on the degradation

of Ms. Bellew's mesh in particular.

b. Reliability

In *Edwards*, I determined that "the process Dr. Iakovlev used to analyze the explant is the industry standard in pathology" and that "[m]ere disagreement among experts is not, in itself, a reason to exclude an expert's testimony." *Edwards*, 2014 WL 3361923, at *25. Therefore, I **ADOPT** my prior ruling on the reliability of Dr. Iakovlev's degradation opinions, as stated in *Edwards*, and **FIND** that he is permitted to opine on the degradation *of Ms. Bellew's mesh.*[3]

2. Nerve Density & Mesh Deformation

In his expert report, when discussing Ms. Bellew's nerve density and mesh deformation, Dr. Iakovlev compares Ms. Bellew's specimen to the transvaginal meshes in his "sample pool." (Iakovlev Report [Docket 121-1], at 93). Because the plaintiff has agreed not to ask Dr. Iakovlev about the other 130 mesh explants he reviewed prior to this case, the defendants' motion with regard to nerve density and mesh deformation is **DENIED as moot** to the extent that Dr. Iakovlev's opinions are based on his "sample pool."

3. Urinary Symptoms

In his expert report, Dr. Iakovlev opines "to a reasonable degree of medical certainty, that the mesh caused the appearance of new urinary symptoms experienced by Ms. Bellew." (Iakovlev Report [Docket 121-2], at 93). The defendants argue that this opinion is unreliable speculation because there are no allegations that Ms. Bellew's mesh was "overtightened." (Defs.' Mem. re: Iakovlev [Docket 122], at 15). Dr. Iakovlev writes that "[t]he specimen shows that the mesh was in contact with muscle bundles consistent with detrusor muscle" and that "[i]t affected nerves and neural ganglia in the area of bladder and urethral innervation." (Iakovlev Report

[3] I also permitted Dr. Iakovlev to opine on mesh degradation with regard to Ms. Eghnayem's mesh based on his "morphological differential diagnosis." *Eghnayem*, 2014 WL 5461991, at *46.

[Docket 121-2], at 93). Because Dr. Iakovlev is able to explain the basis for his opinion that the mesh caused new urinary symptoms, I **FIND** that his opinion contains sufficient indicia of reliability. Accordingly, the defendants' motion with regard to urinary symptoms is **DENIED**. To the extent that the defendants disagree with Dr. Iakovlev's ultimate conclusion, they are free to address that issue on cross-examination.

4. Proposed Testimony

Lastly, the defendants contend that Dr. Iakovlev's proposed testimony significantly exceeds his expertise. (Defs.' Mem. re: Iakovlev [Docket 122], at 15). As discussed more fully above, as a pathologist, Dr. Iakovlev is qualified to opine on the condition of Ms. Bellew's mesh. Therefore, the defendants' motion on this issue is **DENIED**.

IV. The Plaintiff's *Daubert* Motions

The plaintiff moves to limit or exclude the expert opinions of David J. Weber, M.D., M.P.H., Denise M. Elser, M.D., Christina Pramudji, M.D., and Stanley J. Robboy, M.D., F.C.A.P.

A. Motion to Preclude Testimony of Defense Expert David J. Weber, M.D., M.P.H.

The plaintiff seeks to exclude the opinions of Dr. David J. Weber. Dr. Weber is a full professor in the Department of Epidemiology, University of North Carolina Gillings School of Global Public Health with both a medical degree and master's degree in public health. (Weber Report [Docket 114-1], at 3). The defendants requested Dr. Weber to review and comment on scientific and medical literature addressing the use of the Prolift in the surgical treatment of female POP. (*Id.* at 5). In his expert report, Dr. Weber concludes that "[o]verall, the scientific literature demonstrates the Prolift is an efficacious and safe treatment for POP." (*Id.* at 7). The plaintiff argues that Dr. Weber "arbitrarily narrowed the substantial literature on the Prolift and the Gynemesh PS (the mesh material in the Prolift) to a select few articles, based upon no

recognized scientific method or process, excluding the vast majority of relevant literature from his analysis." (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude Test. of David J. Weber., M.P.H. ("Pl.'s Mem. re: Weber") [Docket 115], at 1). The plaintiff takes particular issue with Dr. Weber's decision to define "long-term" as greater than three or more years and his failure to review the Velemir article. (*See id.* at 1, 3).

I find the plaintiff's arguments wholly unconvincing. There is nothing "arbitrary" about Dr. Weber's process. Dr. Weber chose specific search and exclusion criteria based on his years of experience as an epidemiologist and reviewed only literature matching that chosen criteria. (*See* Weber Report [Docket 114-1], at 12-13 ("A PubMed (US National Library of Medicine, National Institutes of Health) search was conducted with MeSH terms 'surgical mesh' and 'pelvic organ prolapse.' All randomized controlled trials since 2005 conducted in humans and published in English were reviewed. All studies that used Prolift or Gynemesh PS in the transvaginal repair of POP in one arm were selected."); *see also id.* at 13 ("A PubMed (US National Library of Medicine, National Institutes of Health) search was conducted with MeSH terms 'surgical mesh' and 'pelvic organ prolapse' and 'follow-up studies[.]' All studies since 2005 conducted in humans and published in English were reviewed. Exclusion criteria included the following: non-epidemiologic study design[;] case series, registries, reviews, editorials; non-Prolift or Gynemesh PS products; less than 3 years follow-up duration; non-vaginal surgery (e.g. abdominal surgery) and, studies with an arm with multiple mesh products.")). Throughout his report and deposition, Dr. Weber explains why he chose the objective criteria he did. (*See e.g.*, *id.* at 7 ("The randomized, blinded (or masked) comparative clinical trial is considered the best design to study a medical intervention (treatment)."); *see also* Weber Dep. [Docket 148-1], at 92 ("The reports were selected solely on the study design and studying of Gynemesh.")).

Furthermore, Dr. Weber did not "decide" to exclude certain literature. (Pl.'s Reply in Further Supp. of *Daubert* Mot. to Preclude Ops. of David J. Weber, M.D., M.P.H. [Docket 163], at 3). Instead, he reviewed the articles that fit the criteria of his search, nothing more, nothing less. If the plaintiff is concerned that certain studies were omitted from Dr. Weber's review, she is free to address that issue on cross-examination. Accordingly, the plaintiff's motion with regard to the reliability of Dr. Weber's expert opinions is **DENIED**.

B. *Motion to Preclude the Testimony of Defense Expert Denise M. Elser, M.D. on the Adequacy of Defendants' Warnings and Pre-Existing Myalgia*

The plaintiff seeks to preclude the testimony of Dr. Denise M. Elser on the adequacy of the defendants' warnings and pre-existing myalgia. (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude the Test. of Denise M. Elser, M.D. on the Adequacy of Defs.' Warnings & Pre-Existing Myalgia ("Pl.'s Mem. re: Elser [Docket 128]). Dr. Elser is board-certified in female pelvic medicine and reconstructive surgery and the Medical Director of Women's Health Institute of Illinois. (Elser Report [Docket 145-1], at 1). The plaintiff argues that Dr. Elser's opinions on the adequacy of the Prolift IFU are unreliable *ipse dixit* opinions and that her opinion that the plaintiff suffered from pelvic floor myalgia before she was implanted with the Prolift is pure speculation. (Pl.'s Mem. re: Elser [Docket 128], at 7, 10). Based on slightly different reasoning than the plaintiff provides, I agree that Dr. Elser's opinions on these two issues should be **EXCLUDED** under *Daubert*.

1. Adequacy of Defendants' Warnings

The plaintiff argues that Dr. Elser's opinions on the adequacy of the Prolift IFU are unreliable because she is unfamiliar with the pertinent regulatory standards and bases her opinions solely on her status and knowledge as a surgeon. (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude the Test. of Denise M. Elser, M.D. on the Adequacy of Defs.'

Warnings & Pre-Existing Myalgia ("Pl.'s Mem. re: Elser") [Docket 128], at 7). In her reply, the plaintiff specifically indicates that she is not objecting to Dr. Elser's qualifications to opine on the adequacy of warnings. (Pl.'s Reply in Further Supp. of *Daubert* Mot. to Preclude Ops. of Denise Elser, M.D. [Docket 160], at 2). However, I have previously determined "that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks [s]he has observed in [her] own practice." *Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *70 (S.D. W. Va. Oct. 17, 2014). The plaintiff's arguments speak to Dr. Elser's qualifications, rather than the reliability of her opinions. Dr. Elser's familiarity with IFUs comes solely from her clinical experience. (*See* Elser Dep. [Docket 127-1], at 37 (Q: [Y]ou're just basing that on your own opinions based on your own experience and what you think is reasonable. Is that fair? A: That's fair.")). In fact, she admits that she did not even know that there were regulations governing what information must be provided in the IFU. (*Id.* at 38). Dr. Elser's understanding of the possible risks associated with pelvic surgery is not sufficient to qualify her to make the broad assertion that *all* possible risks were adequately warned of in the Prolift IFU. Accordingly, consistent with my decision in *Tyree*, I **FIND** that Dr. Elser is not qualified to offer opinions on the adequacy of the Prolift IFU.

2. Pre-Existing Myalgia

The plaintiff contends that Dr. Elser's opinion that Ms. Bellew suffered from pelvic floor myalgia prior to her Prolift implantation surgery is unreliable by Dr. Elser's own admission. (Pl.'s Mem. re: Elser [Docket 128], at 10). In her deposition, Dr. Elser concedes that there is "no objective evidence in any medical record indicating that" Ms. Bellew had pelvic floor myalgia before the Prolift surgery; therefore, her opinion is speculative. (Elser Dep. [Docket 127-1], at 208). The defendants respond by arguing that Dr. Elser discusses pelvic floor myalgia

throughout her deposition and supports her opinion with facts summarized in Ms. Bellew's medical records. (Defs.' Resp. in Opp. To Pl.'s Daubert Mot. to Preclude the Test. of Defense Expert Denise M. Elser, M.D., on the Adequacy of Defs.' Warnings and Pre-Existing Myalgia [Docket 145], at 6). However, the defendants' assertion fails to support their argument.

Throughout her deposition, Dr. Elser clearly states that she does not know whether Ms. Bellew had pre-existing myalgia because she was never tested or diagnosed. (*See id.* at 90 ("So, I don't know what was preexisting[.]"); *see also id.* at 92 ("No, the answer is we don't know. She had complaints of pelvic pain, abdominal pain; and I don't see an assessment of the pelvic muscle tone on the initial evaluation so I don't know what she had."); *see also id.* at 117 ("So, I wish it had been explored more in this patient, but I can't say for sure she has it.")). First, none of these statements by Dr. Elser constitutes an expert opinion because she clearly indicates that she does not have sufficient knowledge to determine whether Ms. Bellew had pre-existing myalgia. Second, nowhere in her expert report does Dr. Elser come to the conclusion that Ms. Bellew had pre-existing myalgia based on her medical records. Although Dr. Elser attempts to connect certain "risk factors" discussed in her report back to her opinion on pre-existing myalgia in her deposition, this connection is not supported by any scientific basis or a differential diagnosis. In her expert report, Dr. Elser's discussion of pre-existing pain is merely a recitation of Ms. Bellew's medical history. Based on my review of the record, the first time Dr. Elser opines that Ms. Bellew may have had myalgia prior to her Prolift surgery is in her deposition. Dr. Elser's opinion is not held to a reasonable degree of medical certainty and was not formed using reliable methodology. Accordingly, I **FIND** that Dr. Elser's opinion that Ms. Bellew had pre-existing myalgia should be **EXCLUDED**.

C. Motion to Preclude the Testimony of Defense Expert Christina Pramudji, M.D. on Particular Issues

The plaintiff seeks to exclude the expert opinions of Dr. Christina Pramudji on "particular issues." (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude the Test. of Dr. Christina Pramudji on Particular Issues ("Pl.'s Mem. re: Pramudji") [Docket 130]). Dr. Pramudji is a board-certified urologist, with a subspecialty board certification of Pelvic Floor Medicine and Reconstructive Surgery. (Pramudji Report [Docket 146-1], at 9). The plaintiff contends that Dr. Pramudji's opinions on (1) the adequacy of the defendants' warnings and (2) smoking are unreliable, and therefore, should be excluded. (Pl.'s Mem. re: Pramudji [Docket 130], at 1). For the reasons discussed below, the plaintiff's motion with regard to Dr. Pramudji **is GRANTED in part** and **DENIED in part**.

1. **Adequacy of Warnings**

The plaintiff argues that Dr. Pramudji's opinions on the adequacy of the Prolift IFU are unreliable because she is unfamiliar with the pertinent regulatory standards and bases her opinions solely on her subjective beliefs and "status" as a surgeon. (*Id.* at 7). In her reply, the plaintiff specifically indicates that she is not objecting to Dr. Pramudji's qualifications to opine on the adequacy of warnings. (Pl.'s Reply in Further Supp. of *Daubert* Mot. to Preclude Certain Ops. of Christina Pramudji, M.D. [Docket 161], at 1). However, I have previously determined "that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks [s]he has observed in [her] own practice." *Tyree*, 2014 WL 5320566, at *70. The plaintiff's arguments speak to Dr. Pramudji's qualifications, rather than the reliability of her opinions. Dr. Pramudji's familiarity with IFUs comes solely from her clinical experience. (*See* Pramudji Dep. [Docket 129-1], at 64-65 ("Q: Well, in determining whether or not the IFU for the Prolift adequately warned of the risks and complications, did you base your

opinion on your own judgment and your own evaluation based on your experience? A: Yes. Q: You did not rely on any particular standards, for example, an FDA regulation or any statement by anyone at Ethicon as to what they were supposed to communicate in those warnings correct? A: Correct.")). In fact, she admits that she is not familiar with any regulations or Ethicon standards governing the Prolift IFU. (*Id.* at 16-17). Dr. Pramudji's understanding of the possible risks associated with pelvic surgery is not sufficient to qualify her to make the broad assertion that *all* possible risks were adequately warned of in the Prolift IFU. Accordingly, consistent with my decision in *Tyree*, I **FIND** that Dr. Pramudji is not qualified to offer opinions on the adequacy of the Prolift IFU. Accordingly, the plaintiff's motion with regard to adequacy of warnings is **GRANTED**.

2. Smoking

Dr. Pramudji opines that the plaintiff's history as a chronic heavy smoker has impeded her healing and contributed to her osteopenia. (Pramudji Dep. [Docket 146-2], at 130-132, 157-158). The plaintiff argues that this opinion is unreliable speculation because Dr. Pramudji "infers causation from risk alone" and fails to perform a differential diagnosis. (Pl.'s Mem. re: Pramudji [Docket 130], at 10). However, Ms. Bellew's medical records reflect that she has struggled with healing in the past. Dr. Pramudji testified that "smoking causes microcapillary damage, so without good blood supply to the vaginal area, the healing is not going to be as robust as it would" and that "[she] know[s] that [Ms. Bellew] doesn't heal well based on her neck surgery where she didn't - - her - - the bone graft didn't take very well at all. And that was attributed to her smoking." (Pramudji Dep. [Docket 129-1], at 136-137). Furthermore, Dr. Pramudji did not perform a differential diagnosis because her opinion is that smoking is a "major contributing factor" with regard to Ms. Bellew's wound healing, not the only factor or cause. (*See id.* at 144). Because Dr. Pramudji is able to explain the basis for her medical opinion that Ms. Bellew's

smoking contributed to her issues with the Prolift, I **FIND** that her opinion contains sufficient indicia of reliability. Accordingly, the plaintiff's motion with regard to smoking is **DENIED**.

D. Motion to Preclude the Testimony of Defense Expert Stanley J. Robboy, M.D., F.C.A.P.

The plaintiff seeks to exclude the expert opinions of Dr. Stanley J. Robboy, M.D., F.C.A.P. Dr. Robboy is a gynecologic pathologist with 45 years of experience and the immediate past-president of the College of American Pathologists. (Robboy Report [Docket 131-1], at 1). Dr. Robboy's expert report discusses "what is expected to be seen following tissue injury, the histologic characteristics of the body's reaction to the implantation of Ethicon's Prolift to treat [POP], a discussion of what is seen in the mesh specimens removed from Mrs. Bellew, and whether histological support exits for Mrs. Bellew's clinical complaints." (*Id.* at 3). Based on his analysis of Ms. Bellew's explanted mesh, among other things, Dr. Robboy concludes that Ms. Bellew's tissue reaction does not explain her symptomology. (*Id.* at 8). The plaintiff argues that Dr. Robboy's expert opinions should be excluded because (1) they are litigation-driven; (2) he failed to perform a reliable differential diagnosis; and (3) he relied on improper anecdotal evidence. (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude Test. of Stanley J. Robboy, M.D., F.C.A.P. ("Pl.'s Mem. re: Robboy") [Docket 132]). For the reasons discussed below, the plaintiff's motion with regard to Dr. Robboy is **DENIED**.

1. **Litigation-Driven**

First, the plaintiff contends that Dr. Robboy's expert opinions are unreliable because they are litigation-driven. Specifically the plaintiff asserts that "before this litigation, [Dr. Elliott has] never been asked to correlate pathological findings to pain" and "has never researched mesh." (Pl.'s Mem. re: Robboy [Docket 132], at 1, 4). An expert's formulation of his opinions for the purposes of litigation does not, by itself, justify that expert's exclusion. *See Daubert*, 43 F.3d at

1317) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture."). This concern, however, does have a role in applying *Daubert*. *See Hoffman v. Monsanto Co.*, No. 2:05-CV-00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007) (considering in the *Daubert* analysis "[w]hether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" (quoting Fed. R. Evid. 702 advisory committee's note)). However, I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable.

Dr. Robboy has largely based his opinions on his professional experience with mesh pathology samples examined during his practice. (Robboy Report [Docket 131-1], at 5, 8). In addition, in his expert report, Dr. Robboy writes that he would have come to the same conclusions had he "received Mrs. Bellew's specimen as 'routine' on the usual surgical pathology bench and not as part of a legal proceeding." (*Id.* at 14). In forming his opinions, Dr. Robboy reviewed Ms. Bellew's medical records and various deposition transcripts, as well as personally examined Ms. Bellew's explanted mesh both grossly and microscopically. (*Id.* at 6). Dr. Robboy's approach in no way indicates he failed to "comport with the dictates of good science." *Daubert II*, 43 F.3d at 1317. Accordingly, the plaintiff's motion with regard to Dr. Robboy's opinions being litigation-driven is **DENIED.**

2. Methodology

Next, the plaintiff argues that Dr. Robboy employs an unreliable methodology because he fails to conduct a proper differential diagnosis in concluding that the mesh did not cause Ms. Bellew's pain. (Pl.'s Mem. re: Robboy [Docket 132], at 4). I disagree. In forming his specific

causation opinions, Dr. Robboy properly relies on his clinical experience, his review of the scientific literature, and his personal examination of Ms. Bellew's medical records and explanted mesh. (*See* Robboy Report [Docket 131-1], at 5-6, 8). This methodology is typical of pathologists, including Dr. Iakovlev, the plaintiff's pathology expert. (Iakovlev Report [Docket 121-1], at 92-94).

With regard to utilizing a differential diagnosis, a plaintiff's expert can rule out alternative causes to determine that mesh, for example, is the most likely cause of the plaintiff's pain. However, as a defendant's expert, Dr. Robboy is ruling out ways in which the mesh could cause pain to come to the conclusion that there is no pathological explanation for the plaintiff's pain. In his expert report, Dr. Robboy explains the various ways in which mesh can cause pain. (*See* Robboy Report [Docket 131-1-], at 15-19 (discussing dyspareunia, nerve entrapment, mesh exposure/erosion, and mesh degradation)). He subsequently concludes, based on his examination of Ms. Bellew's mesh, there is no evidence that her explant caused her pain. (*See e.g.*, *id.* [Docket 131-1], at 16 ("From my review of Mrs. Bellew's specimen and my review of the plaintiff's expert's photographs, it is clear that no traumatic neuroma or any other nerve abnormality that would indicate pain is present, and certainly no atypical one."). I **FIND** this approach sufficiently reliable under *Daubert*. Accordingly, the plaintiff's motion with regard to Dr. Robboy's methodology is **DENIED**.

3. Surgical Specimens

Lastly, the plaintiff argues that "Dr. Robboy's reliance on between 10 to 50 'surgical specimens' of explanted mesh is" improper anecdotal evidence. (Pl.'s Mem. re: Robboy [Docket 132], at 5). The defendants clarify that Dr. Robboy is not attempting to opine on mesh explants outside the context of the present litigation, but instead is merely forming an opinion based on his "knowledge, skill, experience, training, [and] education" stemming from his clinical practice.

Fed. R. Evid. 702; (*see also* Defs.' Resp. in Opp. to Pl.'s *Daubert* Mot. to Preclude the Test. of Stanley J. Robboy, M.D., F.C.A.P. ("Defs.' Resp. re: Robboy") [Docket 151], at 2). In his expert report, Dr. Robboy correlates tissue reactions he has observed in his own practice with the scientific literature. (*See* Robboy Report [Docket 131-1], at 5). Subsequently, Dr. Robboy concludes that

> [b]ased on my experience with other mesh specimens where I have been the examining pathologist, and with earlier extensive experience with cardiac pacemaker electrodes in the heart as well as a 45 year experience with many other tissue types and condition, the overall tissue reaction is mild and does not explain the patient's symptomology.

(*Id.* at 8). In explaining why he thinks Ms. Bellew had a mild tissue reaction, Dr. Robboy identifies various factors "typically expected with mesh specimens." (*See id.* at 15).

The plaintiff takes issue with Dr. Robboy's reliance on his clinical experience because she has no way of "independently verifying" opinions. (Pl.'s Reply to Defendants' Resp. in Opp. to Pl.'s *Daubert* Mot. to Preclude the Test. of Stanley J. Robboy, M.D., F.C.A.P. ("Pl.'s Reply re: Robboy") [Docket 171], at 2). The plaintiff's argument has no practical merit. Numerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions. Such practice can hardly be described as a "mystery." (Pl.'s Mem. re: Robboy [Docket 132], at 5). If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions. Dr. Robboy's reference and reliance on specimens he has previously examined "demonstrates his *experience* with mesh explants and their typical presentation in his normal pathology practice." (Defs.' Resp. re: Robboy [Docket 151], at 4). Furthermore, even where I have previously excluded general causation opinions based on the reliability of the samples, "[an expert's] experience reviewing the mesh in his collection may be relevant to his

qualifications." *Edwards*, 2014 WL 3361923, at *23, n.5 (discussing Dr. Iakovlev's Bendavid study). Accordingly, the plaintiff's motion with regard to Dr. Robboy's surgical specimens is **DENIED.**

V. Effect of *Daubert* Rulings

I emphasize that my rulings *excluding* expert opinions under Rule 702 and *Daubert* are dispositive of their admissibility in these cases, but my rulings *not to exclude* expert opinions are not dispositive of their admissibility. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VI. Conclusion

For the reasons explained above, the defendants' motion with respect to Dr. Jordi [Docket 118] is **DENIED as moot in part** and **DENIED in part.** The defendants' motion with respect to Dr. Mühl [Docket 107] is **DENIED.** The defendants' motion with respect to Dr. Klinge [Docket 101] is **DENIED as moot, DENIED in part,** and **GRANTED in part.** The defendants' motion with respect to Dr. Elliott [Docket 116] is **GRANTED in part, DENIED as moot in part, DENIED in part,** and **RESERVED in part.** The defendants' motion with respect to Dr. Iakovlev [Docket 121] is **DENIED as moot in part, GRANTED in part,** and **DENIED in part.**

The plaintiff's motion with respect to Dr. Weber [Docket 114] is **DENIED.** The plaintiff's motion with respect to Dr. Elser [Docket 127] is **GRANTED.** The plaintiff's motion with respect to Dr. Pramudji [Docket 129] is **GRANTED in part** and **DENIED in part.** The plaintiff's motion with respect to Dr. Robboy [Docket 131] is **DENIED.**

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: November 20, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
ATLANTIC COUNTY
CASE NO. 291 CT
MASTER CASE NO. L-6341-10

- - -

IN RE:
PELVIC MESH/GYNECARE
LITIGATION

- - -

CONFIDENTIAL - ATTORNEYS' EYES ONLY
VOLUME I
Thursday, November 15, 2012

- - -

Oral deposition of DANIEL STEVEN ELLIOTT, M.D., held at MAZIE SLATER KATZ & FREEMAN, L.L.C., 103 Eisenhower Parkway, Roseland, New Jersey, commencing at approximately 9:56 a.m., before Rosemary Locklear, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter (NJ License No. 30XI00171000), and Notary Public.

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I N D E X

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EXHIBIT INDEX

EXHIBIT INDEX (Continued)

			MAR
Elliott			
	6	4-page copy of article dated 11/14/03 entitled "Time Dependent Variations in Biomechanical Properties of Cadaveric Fascia, Porcine Dermis Porcine Small Intestine Submucosa Polypropylene Mesh and Autologous Fascia in the Rabbit Model: Implications for Sling Surgery"	181
	7	6-page copy of article dated 11/11/05 entitled "Time-Dependent Variations In Inflammation and Scar Formation of Six Different Pubovaginal Sling Materials in the Rabbit Model"	190
	8	1-page copy of document dated 10/17/12 entitled "Financial Disclosure of Daniel Elliott, M.D."	214

(Exhibits retained by the court reporter and attached to transcript.)

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with Prolift+M®?

A. No.

Q. Did you ever undergo any of the Prolift® training?

A. No.

Q. I would assume you never underwent Prosima® training either.

A. Correct. I have not.

Q. Why did you switch from Gore-Tex mesh to polypropylene mesh?

A. Because I --

MR. ANDERSON: Objection. Asked and answered.

Go ahead.

THE WITNESS: I was having too many problems with the Gore-Tex, specifically erosion. Extrusion. Excuse me. Vaginal extrusion.

BY MR. SNELL:

Q. And with the Gore-Tex mesh you were having that mesh extrude into the vagina?

A. Correct.

Q. And this was a potential complication that you were aware of during

any indication of a manufacturer.

Q. Well, what's your understanding of what type of material a Silastic graft is?

A. Well, Silastic is Silastic. I don't -- I don't know anything else beyond that.

Q. Is it mono-filament, multi-filament?

A. I don't know.

Q. Is it macro-porous or micro-porous?

MR. ANDERSON: Objection.

THE WITNESS: Yeah. I'm not a biomaterials expert, and I'd have to look at it and measure it and things.

BY MR. SNELL:

Q. Is it a synthetic material?

A. Yes.

Q. The Silastic grafts that you were using for prolapse, do you know if they were FDA approved for the treatment of prolapse?

A. Well, since it was provided to me by a company, I don't know what, I'm going to assume it is.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
ATLANTIC COUNTY
CASE NO. 291 CT
MASTER CASE NO. L-6341-10

- - -

IN RE:
PELVIC MESH/GYNECARE
LITIGATION

- - -

CONFIDENTIAL - ATTORNEYS' EYES ONLY
VOLUME II
Friday, November 16, 2012

- - -

Continued oral deposition of DANIEL STEVEN ELLIOTT, M.D., held at MAZIE SLATER KATZ & FREEMAN, L.L.C., 103 Eisenhower Parkway, Roseland, New Jersey, commencing at approximately 8:25 a.m., before Rosemary Locklear, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter (NJ License No. 30XI00171000), and Notary Public.

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I N D E X

- - -

EXHIBIT INDEX

(Exhibits retained by the court reporter and attached to transcript.)

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I believe you testified yesterday that you've never used or implanted Prolift®; correct?

A. Correct.

Q. Have you ever used or implanted Apogee®?

A. No.

Q. Have you ever used or implanted Perigee®?

A. No.

Q. You never underwent or participated in any of the professional education programs for Prolift®; correct?

A. Correct. I did not.

Q. You never did any cadaver training with respect to Prolift®; correct?

A. I did not.

Q. And you never underwent cadaver training with respect to the use of any mesh products for prolapse repair; correct?

A. No. I'm just trying to remember. In fellowship we may have had cadaver labs on the sacrocolpopexy because our staff was involved in AUA as far as the individual to come in for learning and I may have been

about, the patient-specific issues.

Q. So it's correct, then, that if you can do a transvaginal mesh rescission, you prefer to do so over the transabdominal mesh excision; correct?

A. If it can be safely and successfully accomplished transvaginally, that is, no question, my preferred route.

Q. And that's because transabdominal surgery is a major and morbid surgery; correct?

A. That is fair to say, yes.

Q. Before becoming involved in this litigation, had you ever looked at mesh that had been removed from a patient under a microscope?

A. No.

Q. Have you done that since becoming involved in this litigation?

A. Not of my own patients. I've seen photographs and microscopies and papers.

Q. Prior to being engaged as an expert witness in this matter, had you ever performed any examination of the porosity of

meshes?

A. No.

Q. You don't hold yourself out to be a polymer chemist; correct?

A. That is correct.

Q. If you were counseling a patient on the sacrospinous ligament fixation surgery, what risk would you identify to her with that procedure?

A. Well, I wouldn't have that counsel, consultation because I would send them to my urogynecology colleagues.

Q. Because you don't do sacrospinous ligament fixation procedures; correct?

A. That is correct.

Q. Can you tell me what independent research you did in connection with your role as an expert in this litigation, other than reviewing the materials that plaintiffs' counsel provided to you?

A. Well, I reviewed, as you mentioned, the internal documents, I reviewed roughly, what, 200 manuscripts, scientific journal manuscripts, and then the depositions, which would be the -- from the

litigation.

Q. The internal documents were documents that Mr. Anderson or the other plaintiffs' lawyers gave you; correct?

A. Correct.

Q. Before becoming involved in this litigation, had you ever reviewed any other company's internal documents?

A. Only pertaining to that patent infringement case.

Q. The deposition transcripts, those were given to you by Mr. Anderson or plaintiffs' counsel; correct?

A. Correct. Yes.

Q. The medical literature, the manuscripts that you reviewed, were those given to you by plaintiffs' counsel as well?

A. They gave me a few. So roughly we're looking at 200 or so manuscripts in my report and supplemental report. When this all started, I believe Mr. Anderson gave me 20, maybe 30. So everything else is from me.

Q. So the independent research you did besides reviewing the materials that

plaintiffs' counsel sent to you was you reviewed some of the medical literature and manuscripts.

A. Yeah. It's fair to say that except for what I received from Mr. Anderson and colleagues, everything would be journal reviews.

Q. Do you know any of the study investigators involved in clinical studies concerning Gynemesh® PS?

A. No, I -- I don't know any of those.

Q. Do you know Doug Hale?

A. I don't recognize the name.

Q. Do you know anyone involved in the Prolift® clinical studies?

A. Not that I know of, no.

Q. Now, you've never been employed by the FDA; correct?

A. No.

Q. I'm not correct?

A. No. You are correct. I have never been employed --

MR. ANDERSON: Your bad question.

THE WITNESS: -- or never anticipate being employed by the FDA.

BY MR. SNELL:

Q. Have you ever been a consultant to the FDA?

A. No. The closest would be through that Public Citizen, Ralph Nader's group, where I had comments read at the FDA. But I wouldn't think I would be a consultant for.

Q. Has the FDA ever paid you to be a consultant to provide information to them?

A. No.

Q. Have you ever served on an FDA advisory committee board?

A. No.

Q. Have you ever testified at any government institution, setting aside, you know, the patent case and any other depositions or trial testimony you've given?

A. No.

Q. Have you ever testified at an FDA advisory committee?

A. No. Again, other than that Public Citizen comments. But I was not personally there.

Q. Have you reviewed the federal regulations that pertain to medical devices?

A. No.

Q. Have you ever reviewed any FDA regulations pertaining to devices before becoming engaged as an expert witness in this case?

A. No.

MR. ANDERSON: Off the record.

(Discussion off the record.)

BY MR. SNELL:

Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans.

A. Yes.

Q. What was that?

A. 1998 to '99, it was a new design of an artificial urinary sphincter for men, and I was involved in the original dog studies and then it went into human trials, which my name was on. However, I was not involved because I went down to my fellowship. But my name would be attached to it.

Q. So it's correct that you were not involved in the human clinical trials with regard to this artificial urinary sphincter; correct?

A. I was not involved in the implantation. I was involved heavily as far as the write-up, the documentation. And then timing, I was sent down to my fellowship so I left. I did the work but didn't get to do the surgery.

Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct?

A. Correct.

Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary incontinence synthetic sling; correct?

A. Correct. I have not.

MR. SNELL: Why don't we take a break.

(Recess, 11:15-11:52 a.m.)

BY MR. SNELL:

Q. Doctor, you've never been

involved in a clinical trial designed to assess the safety and efficacy of a stress urinary incontinence device; correct?

A. Correct.

Q. Prior to becoming involved in this litigation, you had never reviewed a device design safety assessment; correct?

A. From an industry, I guess I don't know -- I just want to make sure I'm clear in understanding your question.

Q. Yes.

A. Would this be an industry --

Q. From a manufacturer, yes.

A. No, I have not.

Q. You're not an FDA regulatory expert, are you?

A. No, I'm not.

Q. Yesterday, Doctor, you mentioned the Iglesia study?

A. Yes.

MR. SNELL: Can we mark it as the next exhibit.

(Exhibit Elliott-9 was marked for identification.)

BY MR. SNELL:

residents, you have to look and feel for the mesh. And many times, it's so encased in scar that you have to go by feel, then you can feel the poking sensation of it. It's sharp.

Q. And in the Prolift® mesh that you have examined, you don't recall it being barbed wire; correct?

A. No. I cannot recall. I did not keep records if it was specifically Prolift®. I do know specifically TVT® but not Prolift®.

Q. Can you tell me any clinical human studies in TVT® that reported a barbed-wire effect with the mesh?

A. I don't recall off the top of my head, no. Barbed wire is a descriptive term, not a scientific term.

MR. SNELL: Okay. Let's have some lunch.

(Luncheon recess, 12:29-1:15 p.m.)

AFTERNOON SESSION

BY MR. SNELL:

Q. Am I correct that you never

looked at any FDA guidance documents before becoming involved in this litigation?

A. I'm not familiar what guidance documents are.

Q. As you sit here today, do you know what FDA guidance documents are?

A. No, I do not.

Q. Do you know whether the mesh that was used in sacrocolpopexies by surgeons between the 1970s and the 1990s, whether that use was cleared by the FDA for use in prolapse?

A. I do not know that.

Q. The FDA has never begun, to your knowledge, any type of enforcement proceedings against Ethicon for the Prolift®; correct?

A. I don't know. Proceedings, again, that falls under regulation territory. I'm a clinician. I know of the only -- the event in I believe 2008 where letters were sent, from what I reviewed in depositions, about not having 510 clearance. But I'm not a regulatory individual.

Q. You're not a regulatory expert on 510(k) clearance.

A. By no means.

Q. And you're not a lawyer; correct?

A. No.

Q. You don't have any legal specialization in what is illegal versus legal conduct; correct?

A. Correct.

Q. I'd like to ask you a couple of questions, Doctor, about Exhibit Number 2.

A. Yes.

Q. And this is your November 7th, 2012, supplemental report; correct?

A. Yes, it is.

MR. SNELL: And, again, for the record, we have filed a Motion to strike this report and identified the bases for that. And I'm not waiving any arguments or rights by questioning the doctor on this report.

BY MR. SNELL:

Q. Doctor, in your November 7th, 2012, report, this is the first time that you identified any opinions with regard to

The American Journal of Surgery 193 (2007) 538–542
Research

Differences in polypropylene shrinkage depending on mesh position in an experimental study

Miguel Ángel García-Ureña, M.D., Ph.D.[a,*], Vicente Vega Ruiz, M.D., Ph.D.[a], Antonio Díaz Godoy, M.D.[a], Jose María Báez Perea, M.D., Ph.D.[b], Luis Miguel Marín Gómez, M.D., Ph.D.[a], Francisco Javier Carnero Hernández, M.D.[a], Miguel Ángel Velasco García, M.D., Ph.D.[a]

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Manuscript received January 20, 2006; revised manuscript June 20, 2006

Abstract

Background: Polypropylene (PP) mesh is one of the most frequent materials used in hernia repair. We have experimentally evaluated the shrinkage of PP mesh depending on the place of implantation.
Methods: In 15 New Zealand rabbits a muscular defect measuring 3 × 3 cm was created in both pararectal sides of the abdominal wall. The defect was repaired using a PP mesh measuring 5 × 3.5 cm that was placed in the right side in the sublay location and in the left side in the onlay location. Five animals were killed on the 30th, 60th, and 90th postoperative days. Macroscopic measurement and microscopic study of the prosthesis–host tissue interfaces were performed.
Results: One rabbit was killed because of severe infection in the onlay mesh. Another 2 infections were tolerated in the onlay mesh side. All the prostheses were integrated in the host tissue at death. In the macroscopic evaluation the mesh areas were reduced by 25.92% on the 30th day, by 28.67% on the 60th day, and by 29.02% on the 90th day. The mesh shrinkage was greater in the onlay group than in the sublay group at the 3 time intervals. More inflammatory leukocyte and mononuclear responses also were seen in the onlay group.
Conclusions: These observations support the theory of PP mesh shrinkage as a consequence of the incorporation of the biomaterial to the scarring tissue. This shrinkage is significantly more intense if the meshes are placed in the onlay position. © 2007 Excerpta Medica Inc. All rights reserved.

Keywords: Hernia; Surgical mesh; Polypropylene; Shrinking

Polypropylene (PP) mesh is universally accepted for use in the repair of incisional hernias [1]. This mesh was introduced in 1958 by Usher et al [2], and later was popularized by Lichtenstein [3]. This material has been proven not to be completely inert and does generate an inflammatory response as a foreign body reaction that differs between individuals and depends on the amount of material and the structure of the mesh [4–6]. In fact, late complications such as chronic infection, migration, and erosion have been described.

One of the physical consequences of the inflammatory response to the mesh is shrinking, which has been responsible for recurrences and pain [7,8]. A certain degree of shrinkage, contraction, or folding of the mesh has been reported in experimental models and in some clinical reports during the past 8 years. We also postulated that shrinkage might be the reason for recurrences in the mesh borders after an onlay mesh ventral hernia repair, as seen in our clinical practice. These recurrences were not observed after sublay repairs. The aim of our study was to confirm this contraction in an experimental model and to evaluate possible differences in shrinking depending on the position of implantation.

Materials and Methods

The study was approved by the Cadiz University Committee of Experimental Studies. Fifteen female New Zealand rabbits weighing 2000 to 2500 g were used. The animals followed the European Union guidelines for animal studies (CEE 2871-22A9). All animals were housed in in-

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dividual cages with controlled light/dark cycles, constant temperature, and given free access to water.

All animals were given 150 mg/kg cefazolin 1 hour before the surgical procedure. The anesthesia was induced by an intramuscular injection of ketamine hydrochloride (Ketolar; Parke Davis, Barcelona, Spain) 70 mg/kg and atropine .25 to .3 mL. Additional anesthetic doses were administered in some cases if it was necessary during surgery. Postoperative infiltration with bupivacaine also was used to moderate postoperative pain.

A combined bilateral approach was planned to create 2 groups. An identical defect in the pararectal space was created in either side, a 5-cm long × 3.5-cm wide PP mesh (Trelex, Boston Scientific Corp.) was implanted on the preperitoneal plane (sublay group) in the right side and on the prefascial plane (onlay group) in the left side. Under sterile conditions the animals were shaved and the surgical field was organized with the animal in a supine position. A vertical 5-cm pararectal incision was made in both sides of the anterior abdominal wall. A 3-cm × 3-cm wide defect, including all muscular layers, was created in either side. On the right side the retromuscular preperitoneal space was dissected, the peritoneum was closed with 4/0 polyglactin 910 (Vicryl; Ethicon, Somerville, NJ) suture, and a mesh (5 × 3.5 cm) was laid in the layer sandwiched between the peritoneum and the muscle, fixed with interrupted PP 4/0 sutures. Then, the anterior fascia of the abdominal wall was closed with a 4/0 PP running suture. On the left side the defect was closed with 4/0 polyglactin 910 suture, including all the layers, and a mesh (5 × 3.5 cm) was placed on the prefascial plane fixed with 4/0 interrupted sutures. Finally, the skin was closed with 4/0 nylon interrupted sutures.

Eight hours after surgery the animals were left to feed and drink ad libitum. Five animals were killed 30, 60, and 90 days after implantation. The complete anterior abdominal wall was removed for macroscopic and microscopic evaluations. The presence of tissue integration, infection, denuded areas in the implants, seromas-hematomas, and adhesion formation was recorded. The mesh was isolated in either side and measured in the 4 borders. Tissue samples were obtained from the prosthesis interfaces. Conventional light microscopy was performed on 5-μm slices after fixing in 10% formaldehyde and embedding in paraffin. The specimens were stained in hematoxylin-eosin, Masson's trichrome, orcein, desmin, CD 68, and factor VIII. A morphometric analysis was performed at the interface within 500 μm around the mesh. The partial volume and the percentage of cells were calculated.

Statistical analysis was performed with the nonparametric Wilcoxon rank-sum test to compare measurements between both groups. In addition, a multiple linear regression study was applied. SPSS 11.5 software (SPSS Inc., Chicago, IL) was used.

Table 1
Morphologic data of animals

Day	30	60	90
Preoperative weight	3667.2 (169.8)	2749.0 (365.3)	3953 (300.3)
Weight at death	4993.0 (401.3)	4344.0 (75.5)	5186.4 (483.0)
Preoperative abdominal perimeter	38.5 (1.7)	34.0 (.76)	37.4 (2.3)
Abdominal perimeter at death	42.5 (3.1)	41.0 (1.8)	43.1 (3.7)

Data are expressed as mean (SD).

Table 2
Macroscopic abnormal findings seen at 30, 60, and 90 days after implantation

Findings	Day 30		Day 60		Day 90		Total
	Mesh onlay	Mesh sublay	Mesh onlay	Mesh sublay	Mesh onlay	Mesh sublay	
Infection	1*	—	2	—	—	—	3
Seroma-hematoma	1	—	—	—	—	—	1
Denuded areas	—	1	1	—	1	—	3
Abdominal adhesions	—	—	—	—	—	—	—

* Animal was killed on the 6th day and excluded from the study.

Results

There were no intraoperative complications. One animal developed a severe prosthetic infection of the onlay mesh and was killed on the 6th postoperative day and excluded from the study. No other mesh was removed. The weights and abdominal perimeters of the animals were increased progressively in both groups (Table 1). Two animals killed on the 60th day had mild postoperative wound infections in the onlay side that were treated effectively with local wound cures. These animals had a favorable evolution and were included in the study. The macroscopic abnormal findings on death are shown in Table 2. All the implants were incorporated into the host tissue. Only a few cases showed small denuded areas in the mesh–tissue interface. The detachment of the implant from the abdominal layers was very difficult in both groups, especially when it was situated in the sublay location. In the explanted specimens, we observed folding of the materials in all cases with a perceptible macroscopic appearance of shrinkage (Fig. 1).

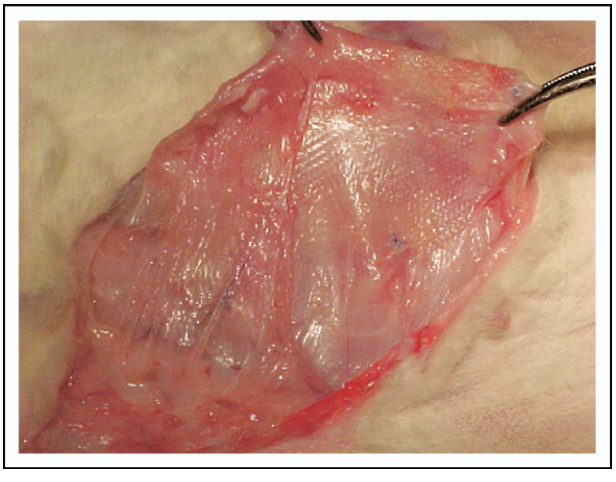

Fig. 1. Macroscopic appearance of shrinkage with foldings of an onlay mesh in an animal killed on the 60th day.

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Table 3
Measurements of mesh at 30, 60, and 90 days after implantation

	Day 30		Day 60		Day 90	
	Onlay	Sublay	Onlay	Sublay	Onlay	Sublay
Length (5 cm)[a]	4.02 (.35)	4.20 (.21)	3.77 (.15)	4.27 (.06)	3.77 (.09)	4.45 (.43)
P value	.012		.012		.005	
Width (3.5 cm)[a]	3.12 (.18)	3.20 (.29)	3.03 (.26)	3.15 (.07)	3.90 (.08)	3.00 (.20)
P value	.018		.012		.005	
Area (17.5 cm^2)[a]	12.44 (1.58)	13.48 (1.88)	11.49 (1.50)	13.46 (.36)	10.94 (.31)	13.40 (1.73)
P value	.012		.012		.005	

Data are expressed as mean (SD).
[a] Initial measurement of mesh at implantation.

In Table 3 the 2-dimensional examination showed a significant shortening of the mesh in length and width on the 30th day ($P = .01$, $P = .01$, respectively), the 60th day ($P = .01$, $P = .01$, respectively), and the 90th day ($P = .005$, $P = .005$, respectively). The implant areas were reduced by 25.92% (onlay, 28.89%; sublay, 22.95%) on the 30th day, by 28.67% (onlay, 34.30%; sublay, 23.05%) on the 60th day, and by 29.02% (onlay, 37.45%; sublay, 23.40%) on the 90th day (Fig. 2).

In the multiple-regression linear analysis the onlay group showed a statistically significant additional shrinking than the sublay group: length, $P = .001$, $R = -.654$ interval of confidence (IC) ($-.6$ to $-.241$); width, $P = .016$, $R = -.468$ IC ($-.43$ to $-.04$); and area $P = .013$, $R = -.440$ IC (-2.5 to $-.32$).

In the microscopic evaluation, all of the meshes were integrated into the host tissues with dense scar tissue. Numerous fibrous bundles were arranged paralleled to the prosthetic surface with areas of fibrinoid necrosis. A number of myofibroblasts also was found among fibrous tissue in the 3 periods of study, more frequently found in the onlay meshes (Table 4). There was also a great inflammatory response with infiltration of polymorphonuclear leukocytes including foreign body reaction (granulomas and giant cells) outlining both sides of the biomaterials. This inflammatory response was slightly more intense in the onlay meshes, and in both groups this infiltrate decreased from the first to the third month. In addition, an increased neoangiogenesis colonizing the connective tissue also was observed in the onlay meshes.

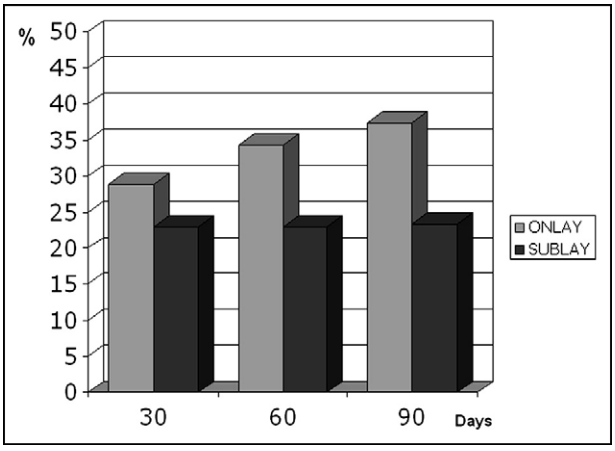

Fig. 2. Percentage of mesh shrinkage for both groups in the 3 periods of death. □, Onlay; ■, sublay.

Comments

Mesh repair is the treatment of choice in abdominal incisional hernias [9]. In the open approach, the PP meshes can be placed in 2 locations safely: onlay, in which the mesh is epifascial on the anterior lamina of the rectus sheath after repair of the defect; and sublay, which is a retromuscular placement of the mesh on the posterior lamina of the rectus sheath or on the preperitoneal spaces. The advantages of the onlay technique are the easier dissection of a risk-free plane over the sheath and the security of laying the mesh far away from the abdominal contents. However, this technique is inconvenient because of the need for an extensive subcutaneous dissection and the limitation of the anatomic boundaries that may restrict the appropriate overlap. Postoperative seromas and infections also are fairly common [10]. The sublay technique promoters advocate that this is theoretically the more correct position to deal with the intra-abdominal pressure forces, and holds the prosthesis against the deep surface of the muscles [11–14]. On the other hand, the longer dissection and separation of the mesh from the abdominal contents is certainly more difficult. There is not enough evidence based on clinical trials to determine whether the sublay location is superior to the onlay location [15]. Our study suggests the benefits of sublay meshes because of fewer infections and less degree of shrinkage.

Despite its high biocompatibility, the PP mesh does generate a foreign body reaction [16]. One of the consequences of this interaction within the host is that the PP material shrinks [7]. Recent studies also have shown that PP meshes are not inert and their pore sizes may reduce in size but also expand when they are exposed to different basic laboratory chemicals [4]. In the same study, a wide range of alterations in pore size, from −40% to 58.5%, also were seen in materials explanted after infection, recurrences, or another surgery. It is important to remember that an increase in pore size is generally equivalent to material shrinkage [17].

Most of the experimental studies with PP meshes have shown a variable grade of shrinkage after different periods of time (Table 5) [18–21], although in some of them this shrinkage was imperceptible [22,23]. Nevertheless, these studies are somewhat heterogeneous because several variables can affect the different outcomes: creation of a muscle

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Table 4
Cellularity (cells/mm^2) at 30, 60, and 90 days after implantation

	Day 30		Day 60		Day 90	
	Mesh onlay	Mesh sublay	Mesh onlay	Mesh sublay	Mesh onlay	Mesh sublay
Mononuclear cells (macrophages, histiocytes, monocytes)	45 (9)	33 (7)	39 (8)	29 (9)	26 (7)	21 (3)
Fibroblasts, myofibroblasts	12 (2)	8 (1)	15 (4)	11 (3)	15 (3)	10 (2)
Vascular cells	37 (6)	18 (4)	34 (10)	16 (4)	33 (6)	14 (1)
Neutrophils	12 (2)	6 (3)	7 (1)	7 (2)	8 (2)	5 (1)
Giant cells	8 (2)	6 (1)	8 (1)	7 (0)	6 (0)	5 (1)

Data are expressed as mean (SD).

and fascial defect, the physiologic growth of the animal, fixation of the mesh, pore size of the mesh, textile structure, weave configuration, fiber diameter, and the quantity of the material.

It is well known that inflammatory reactions also vary between different polypropylene meshes [24] and also between individuals [6]. In a study comparing shrinking of PP meshes with or without fixation after 90 days, the fixation group shrank less and retained their original shapes [18]. Reduction in the amount of implanted PP also generates less inflammatory response [25,26], and larger pore size seems to improve the mature collagen deposition between the fibrils [27]. In a recent study fewer multinucleate giant cells and foci of inflammatory leukocytic exudates were seen in multifilament PP implanted between the erectus spinae muscles in rats [28], although in another study monofilament high-weight PP in an intra-abdominal position showed larger granuloma formation than multifilament PP, but fewer reactions were observed in the monofilament low-weight PP [29]. Our microscopic results showed a slightly more inflammatory response of leukocytes and mononuclear cells in the onlay group. It is possible that the wound healing in the onlay position is subjected to more tensile forces or that the inflammatory response to the mesh also may depend on the interface of surrounding tissues. Another issue that could be assessed in our study was the possible influence on the acute inflammatory response of the mesh of one side to the other. In an experimental study of mesh implantation on both sides of the abdominal wall with PP and polyester, no difference was observed in mesh contraction when a PP mesh was placed near another PP mesh or next to a polyester mesh [21].

In the clinical setting the tendency to shrink also has been described. Amid [7] observed a 20% theoretic shrinkage in a radiographic follow-up evaluation after PP mesh implantation. This contraction of PP materials is particularly remarkable after the use of 3-dimensional meshes. The volume of these plugs has been described to be reduced as much as 70% and may be responsible for some complications attributed to these meshes such as recurrence, migration, and infection [8,30,31]. Mesh contraction also has been observed after the use of other types of materials such as expanded polytetrafluorethylene, polyester, and polyethylene terephthalate [20–23]. In an interesting clinical study the intraperitoneal mesh placement of expanded polytetrafluorethylene considerably reduced the size of the rectus abdominis fascia defect [32]. These investigators attributed this phenomenon to the fibrous ingrowth on the rough surface of the mesh acting as a scaffold for contractile forces of the muscles.

We completely agree with LeBlanc [8] that mesh shrinkage is not a complication of the biomaterial but a consequence of the incorporation of the mesh to a scar tissue that shrinks as it matures. Wound healing is an extraordinarily complex process. At the end of the inflammatory phase, about 4 days under normal conditions, the macrophages provide the growth factors necessary to stimulate the recruitment of fibroblasts, which will play the main role in the incoming fibroplastic phase [33]. This phase is in part mediated by T lymphocytes [34]. During the second week of

Table 5
Published reports that have considered PP mesh shrinkage

Study	PP mesh	Place of implantation	Creation of defect	Animal (number of animals)	Days until death	% area reduction
Klinge et al [19], 1998	Marlex[a]	Sublay (preperitoneal)	No	Dogs (10)	180	34%
Zieren et al [18], 1999	Prolene[b]	Sublay	Yes	Rats (30)	90	17%–22%
Zieren et al [22], 2002	Prolene[b]	Sublay	Yes	Pigs* (12)	100	.01%
Gonzalez and Ramshaw [23], 2003	Marlex[a]	Sublay (preperitoneal)	No	Pigs (6)	96	.02%
Johnson et al [20], 2004	Sepramesh[c]	Sublay (preperitoneal)	No	Rabbits (12)	150	32.6%
Gonzalez et al [21], 2005	Surgipro[d]	Sublay	No	Pigs	90	15%–65%

* Fast-growing animals.
[a] Manufactured by Bard Inc., Murray Hill, NJ.
[b] Manufactured by Ethicon, Somerville, NJ.
[c] Manufactured by Genzyme, Cambridge, MA.
[d] Manufactured by Autosuture-Tyco, Norwalk, CT.

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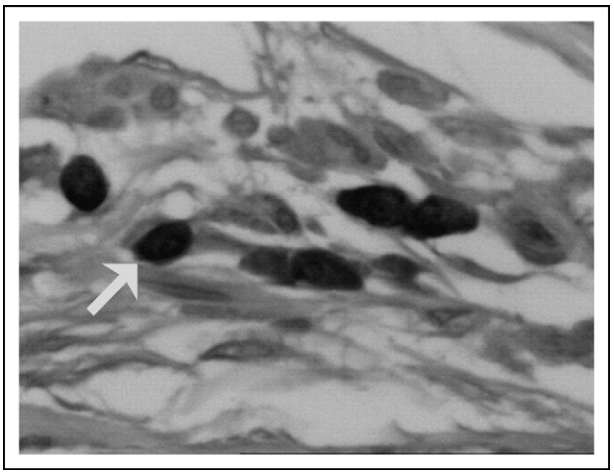

Fig. 3. Histologic appearance obtained at 30 days after implantation. Some myofibroblasts stained with desmin can be seen in the tissue surrounding mesh fibers (arrow).

healing and having started the collagen deposition, some fibroblasts assume a myofibroblast phenotype with large bundles of actin microfilaments (Fig. 3) [35]. The activity of these myofibroblasts is responsible for wound contraction and is stimulated by several growth factors, integrin receptors, and cross-links between collagen filaments. Shrinking of the mesh embedded in wound healing therefore may be attributed to myofibroblasts [17]. In an experimental model of mesh implantation in rats, spindle-shaped fibroblasts increased from months 2 to 4 and stabilized thereafter [36].

We conclude that PP meshes undergo an important degree of shrinkage that occurs during the scarring and remodeling process. In this experimental model this shrinkage has been smaller when the biomaterials were implanted in the sublay retromuscular position than when they were placed using an extrafascial onlay technique.

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ORIGINAL ARTICLE

Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection

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Abstract
Introduction and hypothesis The aim of this study was to evaluate a link between mesh infection and shrinkage.
Methods Twenty-eight Wistar rats were implanted with synthetic meshes that were either non-absorbable (polypropylene (PP), $n=14$) or absorbable (poly (D,L-lactic acid) (PLA94), $n=14$). A validated animal incisionnal abdominal hernia model of mesh infection was used. Fourteen meshes ($n=7$ PLA94 and $n=7$ PP meshes) were infected intraoperatively with 10e6 CFU *Escherichia coli*, and compared with 14 non-infected meshes ($n=7$ PLA94 and $n=7$ PP meshes) (control groups). Explantations were performed on day 30. Shrinkage was evaluated by a reproducible numerical analysis of mesh area. Infection and histological study were evaluated on day 30.
Results Non-infected meshes were less shrunk than infected meshes for both non-absorbable (5.0±1.7% versus 21.6±6.1%, $p<0.05$) and absorbable meshes (2.4±0.9% versus 11.0±2.5%, $p<0.05$).
Conclusion This study highlights a link between infection and shrinkage in the model used.

Keywords Infection · Mesh · Poly (lactic acid) · Polypropylene · Shrinkage

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Introduction

The surgical treatment of genital prolapse using synthetic mesh is restricted by complications such as erosion, infection and shrinkage. Vaginal erosions are well known and may affect more than 10% of patients [1]. They usually require local excision. However, recent publications have reported lower erosion rates (0% to 6.9%), which are therefore close to those observed after laparoscopic or open sacrocolpopexy (3% to 5%) [2].

The biological response of tissues to foreign bodies largely depends on the material and conformation of the mesh [3]. The current literature supports the notion that monofilament polypropylene with a large-pore size induces fewer complications [4]. However, data are not consistently compelling, making it difficult to choose the ideal material [5]. Furthermore, infection is thought to be responsible for erosion, shrinkage, migration of prosthetic devices, and pain [6]. Microorganisms can interfere with the integration process through adhesion to mesh surfaces, and such adhesion is an important stage in the infection [7]. The first stage of adhesion is physical and reversible. The second stage is molecular and irreversible [8]. A subclinical mesh infection, acquired during the initial implantation,

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could result in wound separation with subsequent mesh exposure [9]. Both infection and shrinkage are current problems concerning the treatment of genital prolapse using synthetic meshes.

The aim of this study was to evaluate the link between mesh infection and shrinkage in a validated animal model of mesh infection.

Materials and methods

Shrinkage was studied in relation to the infected or non-infected character of the meshes used. A referent mesh, light-weight PP (Parietene®, Sofradim-Covidien, Trévoux, France), weighting 38 g/m^2, was compared with a new mesh called PLA_{94}. PLA is a long-lasting absorbable polymer that has been used for many years in not only orthopedic and vascular surgery, due to its biocompatibility, but also in preclinic study of our team [10, 11]. We used a thread composed of PLA with 94% L-lactic acid and 6% D-lactic acid (PLA_{94}), which had previously been treated by extraction to remove the surface additive and any agents present in the fibers. A large-pore monofilament mesh composed only of PLA_{94} was used. Time to resorption depends on the level of "L" form containing in the polymer. The resorption time of PLA_{94} is done in 1.5 years; nonetheless, after 8 months, the mesh has no mechanical property anymore. The technical characteristics of the two meshes are outlined in Table 1. Meshes were pre-cut into 30×30-mm patches. Eight 3/0 polypropylene sutures were placed around each implant to facilitate surface area measurements. All meshes used for the study were then sterilized by ethylene oxide, which does not affect their mechanical properties [11].

Ethical committee approval was obtained for the animal study (Ethical Committee Approval number CE-LR-0804).

Rats were housed in an animal facility and treated in accordance with current national guidelines on animal welfare. Twenty-eight Wistar rats (weight range 250 to 300 g) were implanted with synthetic meshes that were either non-absorbable (polypropylene (PP), n=14) or absorbable (poly (D,L-lactic acid) (PLA_{94}), n=14). Fourteen meshes (n=7 PLA_{94} meshes and n=7 PP meshes) were infected intraoperatively with 10e6 CFU *Escherichia coli* and compared with 14 non-infected meshes (n=7 PLA_{94} meshes and n=7 PP meshes) (control groups).

The animals were anesthetized by a mixture of halotane 2.5% and oxygen (0.5 l/min) administered via an inhalation mask, and by an intraperitoneal injection of ketamine (50 mg/kg). The experiments were performed according to the validated incisional hernia rat model described by Alponat et al. [12] and used by Zheng et al. [13]. The abdomen was shaved, disinfected with betadine, and draped to ensure sterile conditions. A vertical midline incision was made through the skin, and skin flaps were raised. A 15×25-mm longitudinal full-thickness defect was created. The defects were repaired with the meshes positioned under the skin but above fascia and muscles. Typically, a mesh was extended 5 mm beyond the cranial and caudal borders and 15 mm laterally. The mesh was laid over the defect with a slight overlap and was sutured without tension to the abdominal wall using interrupted resorbable 2/0 PGA sutures (Vicryl®, Ethicon) at the fourth corners. The peritoneum was left unclosed under the mesh. The meshes were then photographed in vivo using a digital reflex camera (Canon EOS 400D digital), and the area of the mesh was evaluated numerically by ImageJ freeware available on the internet (results in pixels) (Fig. 1). The distance between the camera and the mesh was noted such that the photograph at explantation on day 30 was taken with the same distance between mesh and camera (average 40 cm). The subcutaneous tissues and skin incision were closed with interrupted resorbable 2/0 PGA sutures (Vicryl®). Bacterial inoculation was performed at the end of the surgical procedure according to a validated model of mesh infection previously developed by our team [14], using a small quantity of *E. coli* (10e6 CFU) in order to mimic a subclinical mesh infection.

The animals were checked daily for local or systemic complications throughout the entire 30-day observation period. Explantations were performed on day 30. The meshes were photographed in vivo using the same reflex digital camera previously used, and mesh area was again evaluated numerically by the software (Fig. 2). The initial implants, with their neighboring host tissues, were resected. On retrieval, the meshes were cut into two strips for both histological and bacteriological study.

An uropathogenic *E. coli* (UPEC) strain previously isolated from a patient with UTI (NECS19923) and harboring the main virulence factors (e.g., toxins, adhesins, siderophores, and capsules) registered in UPEC was used.

Table 1 Comparative technical characteristics of the implanted meshes

Name	Type of textile	Filament	Structure	Coating	Pore size (mm)	Amid classification	Weight (g/m^2)
None	PLA_{94}	Mono	Knitted	No	Macroporous (3.5×1.7)	I	100
Parietene light	PP light	Mono	Knitted	No	Macroporous (1.5×1.7)	I	38

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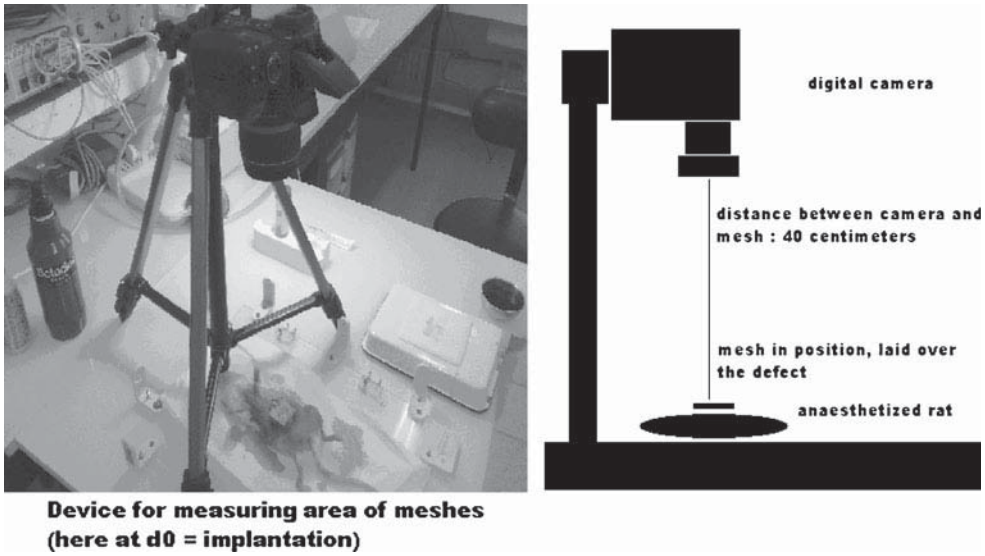

Fig. 1 Mesh contraction was evaluated by measuring mesh area pre- and postoperatively using a standardized protocol of in vivo mesh photography. Pictures of anesthetized rats at a distance of 40 cm were taken, before skin closure preoperatively and after skin incision on day 30

The bacteriologist was blinded with regard to mesh identity. Strips samples were placed in 2 ml Muller–Hinton broth, crushed with a sterile scalpel, and incubated at 37°C for 18 h. Colonies were counted after serial dilution. Different standard agar plates were used to identify and isolate the bacteria that grew around the meshes. Genus and species were determined biochemically using the API identification card (bioMérieux, Marcy l'etoile, France). Post-infection *E. coli* strains were identified by genetically comparing randomly collected colonies with NECS19923 on the basis of their virulence profile.

The investigator for the histopathological examination was blinded to the mesh. For each histology strip sample (one per mesh explanted), three slides were stained with Masson's trichrome, and three slides with hematoxylin and eosin (H&E). The microscopic evaluation quantified the presence of polynuclear, mononuclear, and giant cells; newly formed vessels in H&E-stained sections; and collagen (organization, composition, and amount). Five fields per slide were counted at ×400 magnification (Olympus AX70 Provis, Japan). The scale used was similar to that described by Zheng et al. [13].

Data were summarized by frequency and percentage for categorical variables and by mean, standard deviation, median, and range for continuous variables. To investigate the association between categorical variables, univariate statistical analyze were performed using Pearson's chi-2 test or Fisher's exact test if the sample size was small and using Wilcoxon's test or Student's *t* test for continuous variables. In order to account for the number of tests performed, the alpha risk was corrected using the Bonferroni method. All statistical tests were two-tailed, and a *p* value of less than 0.05 was considered statistically significant. All statistical tests were performed using SAS v.9 statistical software (SAS Institute, Cary, NC, USA).

Results

Four animals died during the experimental period (14.3%): one in the PLA_{94}-infected group, two in the PP-infected group, and one in the PP non-infected group. One died after anesthesia and three because of postoperative evisceration. None died because of infection. Tests conducted on day 30 showed that no *E. coli* were present on the mesh in non-infected animals. In the opposite group, the NECS19923 strain was found in all infected animals and there was at least 10e5 CFU. Contamination with *Staphylococcus epidermidis* was possible, but always less than 10e5 CFU, and did not correlate with mesh shrinkage.

Non-infected meshes were less contracted (2.4±0.9% for PLA_{94} and 5.0±1.7% for PP) than infected meshes (11.0±2.5% for PLA_{94} and 21.6±6.1% for PP) after 1 month of implantation ($p<0.05$). Moreover, absorbable PLA_{94} meshes contracted less than non-absorbable PP meshes when infected (11.0±2.5% versus 21.6±6.1, $p<0.05$) (Table 2). Histological results are shown in Table 3.

Discussion

Three recent randomized controlled trials have showed that mesh repair was superior to anterior colporrhaphy in pelvic floor reconstructive surgery [15–17]. Low-weight polypropylene meshes were used by Hiltunen et al. [15], and the rate of recurrence was better with it than with colporrhaphy repair. Nguyen and Burchette [16] also found less recurrence of prolapsed using polypropylene than without. Sivaslioglu et al. [17] concluded in their study that surgery with light polypropylene mesh (Sofradim, Parietene) is superior in terms of anatomical results to the site-specific surgery in the treatment of cystocoeles. Local complica-

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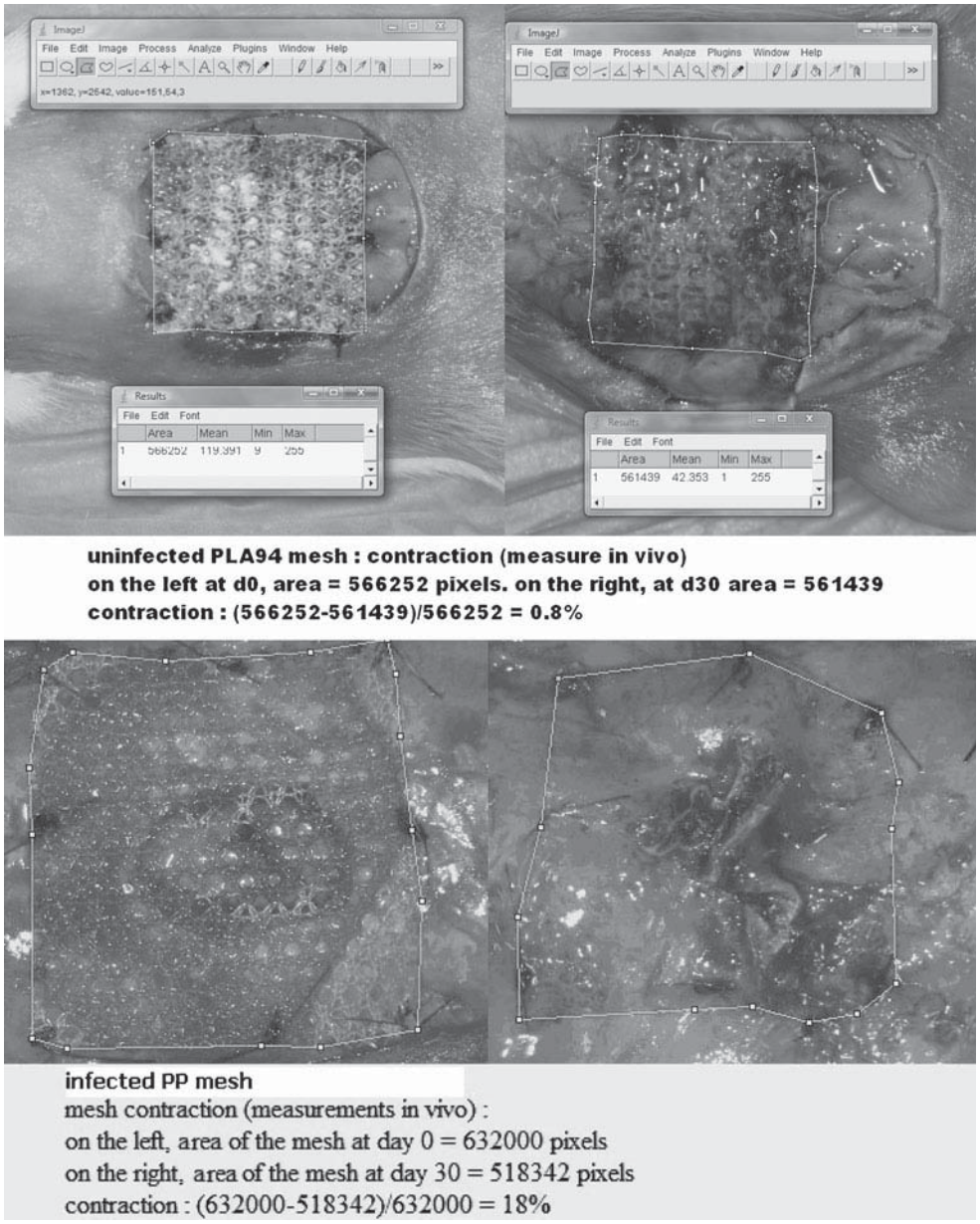

Fig. 2 Examples of mesh contraction measurements using Image J software

tions, such as erosion, shrinkage, pain, dyspareunia, and infection, are still important limitations, particularly in young and sexually active women.

Whereas the pathophysiology and management of vaginal erosion are now well known, little information is available on mesh shrinkage. Although this phenomenon is poorly defined, its incidence poorly reported, and its pathophysiology and risk factors unclear, it may be responsible for major local complications such as pain and dyspareunia, and also recurrences, with subsequent difficult reinterventions.

Hypotheses explaining mesh shrinkage include an inflammatory reaction around the mesh, itself correlated with weight and pore size, and an immunological reaction, which we have not found in our study, probably due to a lack of power. In the present study, we put forward the hypothesis that infection of the mesh caused by bacterial contamination during the implantation phase is an independent risk factor for shrinkage. When working with two different meshes, we observed a significant correlation between infection and shrinkage.

Tissue ingrowth around synthetic implants is a complex phenomenon, indissociable from the inflammatory reaction. An immunochemical analysis of infected implanted mesh would be of great interest, with a particular focus on TGF-beta1 which is a determinant of foreign body reaction to alloplastic materials in rat fibroblast cultures [18]. This type of study should be able to differentiate between the respective responsibilities of bacterial contamination and non-infectious foreign body reactions in mesh shrinkage.

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Table 2 Results for infection and contraction

Meshes	Samples	Death	Infection on day30 (mean CFU)	Contraction (%±SD)	*p*
Non-infected PLA_{94}	7	0	0	2.4±0.9	–
Infected PLA_{94} (*E. coli* 10e6 CFU)	7	1	7 (5×10e5)	5±1.7	<0.05[a]
Non-infected PP	7	1	0	11±2.5	–
Infected PP (*E. coli* 10e6 CFU)	7	2	7 (2×10e6)	21.6±6.1	<0.05[b]

PLA_{94} poly (lactic acid) mesh, *PP* polypropylene mesh

[a] The difference between infected PLA meshes and non-infected PLA meshes is significant in term of shrinkage ($p<0.05$): The infected one are more shrunk

[b] The difference between infected PPL meshes and non-infected PPL meshes is significant in term of shrinkage ($p<0.05$): The infected one are more shrunk

However, intraoperative bacterial contamination of synthetic implants is rather uncommon in clinical practice; although clinical infection such as abscess is rare, subclinical chronic infection may explain several local complications. This has already been observed in mesh exposure after wound separation due to infection [9]. Further studies are necessary to confirm our hypothesis using more animals, animal models for vaginal surgery, and longer-term experiments. Should the hypothesis be confirmed, the use of antibacterial products on synthetic implants would be greatly beneficial in women.

Mesh shrinkage has been reported to occur early after tissue implantation, within the first 14 days of tissue healing in response to the acute inflammatory reaction [19]. After this early phase, mesh shrinkage defined as surface loss measured in millimeters and expressed as a percentage of initial surface area, and which occurs in 72% of all implants, was stable over a 180-day period in a rabbit abdominal model where it correspond to 3–20% of the initial surface area [19].

E. coli isolate was used because this strain is common in vaginal infections [20] and is the most frequent in infected biomaterial [21]. Prosthesis infection often springs from the transformation of a usually non-pathogenic colonizing bacterium into virulent colonies that adhere to the material [21]. A low infection level (10e6 UFC) was injected intraoperatively on the mesh in order to mimic a subclinical bacterial contamination of the mesh.

As previously shown [10], mesh was better tolerated in the PLA_{94} than in the PPL groups, and PLA_{94} is also less likely to be infected than PPL, which could contribute to improving biocompatibility, but our results are not significant probably due to a lack of power. Anyway, PLA_{94} did shrink less than PPL. A better tolerance and a lower degree of infection with a better integration of the mesh could explain the difference; physical reasons may explain the difference, including different hydrophilic surface properties, which could influence bacteria colonization [22]. Furthermore, research with more power would be interesting in order to find out a link between shrinkage, infection, and integration of meshes.

In conclusion, shrinkage, which is a complex phenomenon occurring during tissue healing around synthetic biomaterial, may be significantly influenced by both the polymer used for the implant and intraoperative bacterial contamination around the mesh. To explain the mechanism of shrinkage with infection, more powerful studies are needed. Are the meshes less integrated when infected? Mechanical strength tests and histological studies with more effective power would be

Table 3 Histological results (scores from 0 to 3)

Meshes	Mononuclear cells	Polynuclear cells	Foreign body giant cells	Vascularity	Collagen organization	Collagen composition	Collagen amount
PLA_{94}, $n=7$	1.43[a]	0.71	0.29	2.86	2.71	2.43	2.71
Infected PLA_{94}, $n=6$	2	0.83	0.33	2.5	2.5	2.67	2.8
PP, $n=6$	2.5	1.33	1	2.17	2	1.83	2
Infected PP, $n=5$	2.8	1.4	0.8	1.6	1.86	2	2
p[b]	0.43	1.0	1.0	0.18	0.84	0.68	1.0

PLA_{94} poly (lactic acid) mesh, *PP* polypropylene mesh

[a] Results: average score of the parameters

[b] Statistical comparison between the 14 non-infected meshes and the 14 infected meshes

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interesting. These observations are critical if the local complications of synthetic mesh placement by the vaginal route are to be reduced.

Conflicts of interest This study represents a master thesis funded by Covidien. Renaud de Tayrac is a consultant for Covidien. The other co-authors have no conflict of interest.

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Vaginal Mesh Contraction

Definition, Clinical Presentation, and Management

Benjamin Feiner, MD, and Christopher Maher, MD

OBJECTIVE: While transvaginal polypropylene mesh is increasingly used in the management of pelvic organ prolapse, contraction of the mesh after implantation may cause substantial morbidity. This report defines the clinical entity of vaginal mesh contraction.

METHODS: This is a case series of women who underwent surgical intervention for the management of symptomatic vaginal mesh contraction in our tertiary referral urogynecology center between January 2007 and December 2008. We evaluated the presenting symptoms, examination findings, subsequent management, and outcome.

RESULTS: Seventeen women with vaginal mesh contraction were included in this series. Clinical presentation included severe vaginal pain, aggravated by movement (17 of 17), dyspareunia in all sexually active women (14 of 14), and focal tenderness over contracted portions of the mesh on vaginal examination (17 of 17), commonly involving the lateral fixation arms. Mesh erosion (9 of 17), vaginal tightness (7 of 17), and shortening (5 of 17) were frequently present. Surgical intervention consisted of mobilization of the mesh from the underlying tissue, division of fixation arms from the central graft, and excision of contracted mesh. After surgery, 88% (15 of 17; 95% confidence interval 73–104) of women have experienced substantial reduction in vaginal pain and 64% (9 of 14; 95% confidence interval 39–89) experienced substantial reduction in dyspareunia. Three women required subsequent excision of the entire accessible mesh because of persisting symptoms.

CONCLUSION: Vaginal mesh contraction is a serious complication after prolapse repair with armed polypropylene mesh that is associated with substantial morbidity, frequently requiring surgical intervention. Research and development is urgently needed for newer graft materials with diminished shrinkage properties.

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LEVEL OF EVIDENCE: III

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Preliminary data from this project was presented in oral abstract form at the 33rd annual scientific meeting of the International Urogynecological Association, June 16–20, 2009, Taipei, Taiwan.

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High failure rates after conventional surgeries for pelvic organ prolapse (POP) have led to the introduction of graft materials to the field of pelvic floor reconstruction, aiming to reinforce the native tissues and achieve improved functional and anatomical outcomes. While recent randomized controlled trials have demonstrated that synthetic mesh at the anterior vaginal compartment reduces the risk of prolapse recurrence as compared with anterior colporrhaphy at 1 and 2 years,[1–4] there is no level I evidence to support the use of vaginal polypropylene mesh for apical or posterior compartment prolapse.[5] Commercial polypropylene repair kits are available and typically consist of a prestyled mesh graft with fixation arms that travel through the obturator foramen for anterior compartment reinforcement or through the ischiorectal fossa for the posterior and apical compartments. More recently device related complications have been reported,[6–9] and in October 2008 the U. S. Food and Drug Administration (FDA) published a special notification titled "Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence." In this release, the U. S. Food and Drug Administration describes more than 1,000 reports from manufacturers of mesh and mesh-based kits of complications associated with these products. The most frequently reported complications included mesh erosion through the vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. A few months before that, Ridgeway et al (Ridgeway B, Walters

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MD, Paraiso MF, Barber MD, McAchran SE, Goldman HB, et al. Early experience with mesh excision for adverse outcomes after transvaginal mesh placement using prolapse kits. Presented at the 34th Annual Scientific Meeting of the Society of Gynecologic Surgeons, April 2008, Savannah, GA) reported their early experience with mesh excision for a variety of adverse outcomes.

While in vivo shrinkage of polypropylene mesh up to 50% of its original size has been previously demonstrated both in animal models[10] and in women,[11] the clinical implication of this biomechanical characteristic remains undefined. During the last 2 years a number of patients who developed substantial morbidity related to mesh contraction have been treated in our unit and despite attempts of conservative management the majority required surgical intervention. The aim of this report is to define the clinical entity of vaginal mesh contraction.

MATERIALS AND METHODS

This case series describes the presenting symptoms, examination findings, subsequent management, and outcome of women who underwent surgical intervention for the management of vaginal mesh contraction after prolapse repair with armed polypropylene mesh kits. The study was approved by the Institutional Review Board at the Royal Brisbane & Women's Hospital. Consecutive women who underwent surgery for symptomatic mesh contraction between January 2007 and December 2008 were included in this series. Women with other mesh-related complications (erosion, infection, etc) without associated contraction were excluded. The medical records of all patients were reviewed by the principal author (B.F.), a urogynecology fellow, and relevant information collected including demographics, medical and obstetric history, previous surgeries, presenting symptoms and examination findings, details of conservative and/or surgical management, and outcome. The clinical evaluation consisted of abdominal palpation, speculum visualization of the vagina including prolapse quantification using the International Continence Society POP-Q system,[12] and bimanual vaginal and rectal examination. On bimanual examination the clinician carefully palpated all areas of the vaginal epithelium. Any abnormal findings such as focal or diffuse tenderness, increased mesh tension, or the presence of prominent bands under the vaginal mucosa were recorded. Descriptive statistical calculations including means, medians and standard deviations were used for demographic parameters and 95% confidence intervals (CIs) were calculated as part of the outcome analysis of the surgical interventions.

To identify previous publications on this entity we searched the Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews and Effects, American College of Physicians Journal Club and MEDLINE (1950 to June 2009) using the terms "vaginal mesh contraction," "mesh complications," and "mesh shrinkage." No language limitations were used. We also hand-searched conference proceedings of the International Urogynecological Association, the International Continence Society, the American Urogynecologic Society, and Society for Gynecologic Surgeons between January 2007 and June 2009.

All women initially underwent a variety of conservative management including topical estrogen therapy, pelvic floor muscle exercises, and vaginal dilators. Women with persisting symptoms underwent surgical intervention. All surgeries were performed by the two authors of this manuscript, ie, a consultant urogynecologist and a urogynecology fellow, in operating theater setting with the patient under general anesthesia.

An examination with the patient under anesthesia is performed, and the areas of contracted mesh, including any involved mesh arms, are identified by palpation. The vaginal epithelium covering the mesh is infiltrated using 0.25% bupivacaine with 1:400,000 adrenalin for hydrodissection and hemostasis. The vaginal epithelium is incised with a scalpel and dissected off the underlying tissue using sharp dissection with Metzenbaum scissors. The mesh is identified and grasped with Moynihan forceps. With counter-traction applied by the forceps, the mesh is gently dissected off the bladder or rectum using scissors. The plane of dissection has to be parallel to the mesh, and the tips of the scissors should point away from the underlying viscus to avoid inadvertent injury. When dissecting laterally to mobilize contracted mesh arms, medial traction of the mesh is valuable to improve visualization and access. The mesh arms should be transected as lateral as possible, and any contracted areas of mesh should be excised. Not uncommonly the mesh is firmly adhered to the fascia and cannot be safely removed in one step. In these cases it should be mobilized and removed in a piecemeal fashion. It is typically more difficult to define the extent of the contracted mesh once the vaginal epithelium has been incised and dissected. Therefore it is highly important to determine the affected area before the first incision. The same surgical principles apply in cases in which removal of the entire mesh is indicated due to failure of a previous partial excision to alleviate

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symptoms. In these cases, the central body of the mesh and the arms medial to the pubic rami at the anterior compartment and to the sacrospinous ligament at the apical compartment are excised. After satisfactory hemostasis is obtained, the vaginal epithelium is approximated using 2/0 Polyglactin absorbable suture (Vicryl, Ethicon, Somerville, NJ). In cases of concomitant mesh erosion, distal from the site of contraction, the surrounding vaginal epithelium is mobilized from the underlying mesh using sharp dissection, and the eroded mesh is grasped with Moynihan forceps and excised until no mesh is visible or palpable underneath the epithelial edges. The vaginal epithelium is then oversewn. At the end, cystoscopy and rectal examination are performed to ensure bladder and rectal integrity, the vagina is packed, and an indwelling urethral catheter is inserted overnight.

RESULTS

Seventeen women were included in this review. Ten of these women (60%) underwent the initial mesh repair in different institutions and were referred to our tertiary referral center for the management of their adverse postoperative outcome. Seven were originally operated on by our team and are included in an ongoing analysis to be published in the future, which will help estimate the incidence of this complication.

Demographics and surgical history are detailed in Table 1. All women had previously undergone armed polypropylene mesh reconstructive surgery, and in 65% of women (11 of 17) this was the primary intervention for POP. None of the patients underwent further interventions between the mesh implantation and presenting to our unit. In all cases the type of mesh kit used for prolapse repair was either anterior mesh alone or combined anterior and posterior mesh kits. The Total Prolift system (Ethicon Women's Health and Urology, Somerville, NJ) was used in six women (35%), Anterior Prolift and Perigee (American Medical Systems Inc., Minnetonka, MN) systems were used in four patients (24%) each, and Apogee–Perigee in conjunction was used in three women (18%). All included patients failed to respond to conservative management and required at least one surgical intervention. The median (range) time from mesh implantation to seeking medical care for symptomatic mesh contraction was 20 (4–52) weeks.

The presenting symptoms and examination findings are detailed in Table 2 and demonstrate that 100% of women had severe vaginal pain, which was aggravated by movement, and all sexually active women experienced severe dyspareunia. On vaginal examination all women had prominent tense focal areas of mesh palpated under the vaginal epithelium. In 82% (14 of 17) of the women the junctions between the fixation arms and the main body of the mesh were the focal site of tension, with the proximal arms of the anterior mesh accounting for 71% (10 of 14) of cases. In all the women palpation of the localized prominent tense mesh under the vaginal mucosa reproduced the pain the patients experience with movement and intercourse.

The extent of surgical intervention performed was proportional to the severity of symptoms and physical findings, and the various procedures are detailed in Table 3. Median (range) postoperative review was 24 (6–84) weeks, and Table 4 presents the clinical outcome of the surgical management. Eighty-eight percent of women (15 of 17, 95% CI 73–104) had resolution of the vaginal pain after the primary surgery, and 64% of sexually active women (9 of 14, 95% CI 39–89) experienced substantial reduction in dyspareunia. Three patients who had persisting symp-

Table 1. Demographics and Surgical History

Variable	
Age [mean y±SD]	54.9±11.7
Parity [median (range)]	2 (1–6)
BMI [mean kg/m^2±SD]	27.6±5.8
Previous hysterectomy [n (%)]	11 (65)
Previous prolapse repair with polypropylene mesh kit [n/N (%)]	17/17 (100)
Prolapse surgery prior to mesh implantation [n/N (%)]	6/17 (35)

SD, standard deviation; BMI, body mass index.

Table 2. Clinical Presentation of Women With Vaginal Mesh Contraction

	n (%) (N=17)
Symptoms	
Severe vaginal pain	17 (100)
Dyspareunia	14 (100*)
Vaginal discharge/spotting	3 (18)
Male discomfort	1 (7*)
Awareness of prolapse	1 (6)
Examination findings	
Focal vaginal tenderness over contracted mesh	17 (100)
Prominent tender band(s) over mesh arm(s)	14 (82)
Vaginal tightness	7 (41)
Foreshortened vagina (TVL less than 7 cm)	5 (29)
Mesh erosion	9 (53)

TVL, total vaginal length.
* Value represents the percent of the sexually active women.

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Table 3. Surgical Procedures

Intervention Arm	n (%)
First intervention (n=17)	
A	3 (18)
B	3 (18)
E	1 (6)
A+C	1 (6)
B+C	2 (12)
B+D	3 (18)
B+C+D	2 (12)
C+D	2 (12)
Second intervention (n=3)	
E	3 (100)

A, mobilization and division of mesh arms (without excision); B, excision of mesh arms; C, partial excision of the central mesh graft; D, management of mesh erosion; E, excision of the entire accessible mesh.

toms with further tense areas of contracted mesh on examination underwent complete excision of the accessible mesh, resulting in substantial reduction in pain. One of the three reported on resolution of the dyspareunia after the intervention, and two had not been sexually active yet at the time of the review. One woman presented with multiple mesh erosions and a multifocal contraction after a Perigee mesh implantation, and therefore the entire mesh was excised at the first surgical intervention. Another woman who underwent complete excision of the mesh subsequently presented with a recurrent symptomatic vault and anterior vaginal prolapse, and a laparoscopic sacralcolpopexy and paravaginal repair were performed at a later stage.

In summary, in our review all women presented after undergoing prolapse repair with transvaginal armed polypropylene mesh and experienced severe vaginal pain and dyspareunia (those who were sexually active) subsequently. On a thorough vaginal examination localized areas of prominent tense mesh were noticed under the vaginal epithelium in all the patients. Palpation of the contracted mesh reproduced the pain these women experienced with movement and sexual intercourse. After primary surgical intervention to release the tension caused by the contracted mesh, 88% of patients had resolution or substantial reduction of the vaginal pain. All women had resolution of the pain if including the three who underwent further excision of the entire accessible mesh.

Table 4. Outcome After Surgical Intervention

Outcome	Proportion of Women (%)
Outcome after first intervention	
Substantial reduction in vaginal pain	15/17 (88)
Substantial reduction in dyspareunia	9/14 (64)
Sexual discomfort due to foreshortened vagina	1/14 (7)
Minor improvement only/no change	2/17 (12)
Outcome after second intervention	
Substantial reduction in vaginal pain	2/2 (100)
Substantial reduction in dyspareunia	1/3 (33)
Not sexually active yet	2/3 (66)

After evaluating the presenting symptoms, examination findings, and outcome analysis we define vaginal mesh contraction as an adverse outcome after prolapse repair with armed polypropylene mesh in women who experience vaginal pain with movement and dyspareunia and on examination have localized areas of prominent tense and tender mesh under the vaginal epithelium.

DISCUSSION

In this report we describe the clinical presentation, surgical management, and outcome of women with vaginal mesh contraction after pelvic organ prolapse repair with armed polypropylene mesh kits. The main clinical features include severe vaginal pain with movement, dyspareunia, and focal tenderness over contracted portions of the mesh on vaginal examination. This is the first article to define the clinical entity of vaginal mesh contraction as well as the largest series written on this adverse surgical outcome as confirmed by our thorough literature search, in which we were unable to locate any series defining or relating to the clinical implication of this entity.

Although shrinkage of synthetic mesh after implantation had been reported by Amid et al[13] as early as in 1997, the etiology of this phenomenon is still unknown, and different theories have been suggested. García-Ureña et al[10] considered graft shrinkage to be a physical consequence of the inflammatory response to the mesh, while Gonzalez et al[14] argued that it is a result of inadequate tissue ingrowth into the mesh. While the pathophysiology remains unclear, there is growing evidence to suggest that synthetic mesh shrink significantly once incorporated in the biological tissues. This evidence emerges both from animal studies, in which the rate of shrinkage can be directly assessed by comparing the graft's area preoperatively and postoperatively,[10] and from human studies involving mesh for hernia or prolapse repair.[11] Using imaging techniques such as ultrasonography or magnetic resonance imaging, the dimensions of the graft can be assessed postoperatively and compared with those of the original mesh. More recently Letouzey et al (Letouzey V, Deffieux X, Levaillant J, Faivre E, de Tayrac R, Fernandez H. Ultrasound evaluation of

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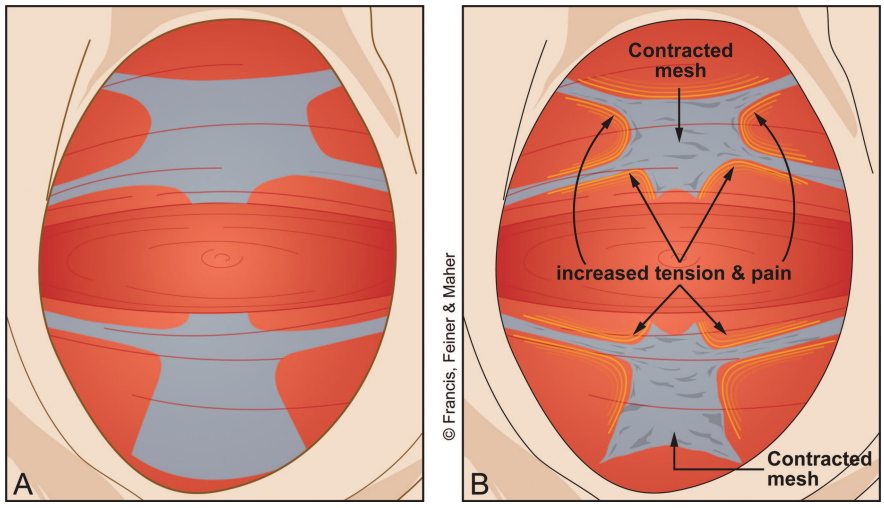

Fig. 1. Illustration of anterior and posterior vaginal mesh layout, showing an anterior mesh with four arms above and a posterior mesh with two apical arms below: at implantation **(A)** and after the body of the mesh has contracted by 30% **(B)**. Increased tension is demonstrated by the narrowing of the arms, and areas of pain are demonstrated by curved lines. Illustration: Stephen Francis. Copyright ©2009, Francis, Feiner, and Maher.

Feiner. Vaginal Mesh Contraction. Obstet Gynecol 2010.

polypropylene mesh contraction at long term after vaginal surgery for cystocele repair. Presented at the 34th Annual Scientific Meeting of the International Urogynecological Association, June 2009, Lake Como, Italy) reviewed the long-term changes in mesh volumes over time using three-dimensional translabial ultrasonography and found mean contraction of 30%, 65%, 85% at follow-up durations of 3, 6, and 8 years, respectively. This study demonstrates that the pathological process that causes mesh shrinkage is progressive and there is a linear evolution of the contraction rate with time, raising the worrying possibility that mesh contraction syndrome that we have defined may be encountered more frequently in the future.

The present study however focuses on the clinical expression of mesh contraction rather than on the biomechanical phenomenon. All of the women included in this series had a clearly palpable painful mesh contraction that brought them to seek medical care. In the majority of cases the most severe tenderness on vaginal examination was present at the junctions between the central mesh graft and the fixation arms as a result of excessive tension after shrinkage of the main body of the mesh against the serrated arms that remain fixated and unmovable in the tissue (Fig. 1). This tension is also likely to be responsible for the extremely high erosion rate (53%) seen in this group of patients as compared with published data on polypropylene mesh erosion rates after prolapse repair (5–20%).[2,15] An alternative explanation for the pathophysiology of this scenario can be either excessive tensioning of the arms or bunching of the mesh at implantation. The manufacturer's instructions and mentoring programs all stress the importance of a tension-free insertion of the mesh as a flat sheet without bunching. The use of vaginal pack postoperatively is nearly universal and further acts to reduce the likelihood of both bunching of the graft and excessive tension on the fixation mesh arms.

The goal of our surgical management was to relieve the tension by dividing the central graft from the arms and excising all areas of mesh contraction. This approach led to a substantial reduction in the vaginal pain in 88% of women and in dyspareunia in 64% after the primary intervention. Further improvement was reported by women who underwent a subsequent removal of the entire accessible mesh. This surgical intervention however is potentially associated with an increased risk of visceral injury and hemorrhage as the tissue is often firmly adhered to the mesh and surgical planes rarely exist. Moreover, re-approximation of the vaginal epithelium after excision of the mesh is often challenging as the vaginal tissue itself is typically scarred and fragile in areas of mesh contraction.

The retrospective nature of this study is associated with possible weaknesses, including failure to adequately document pre–mesh insertion morbidity, which is exacerbated by the fact that 60% of the patients had their initial interventions performed in other institutions, where variability in indications for surgery and in surgical techniques exist. A further weakness is the inability to estimate the incidence of symptomatic mesh contraction as opposed to asymptomatic shrinkage. Finally, three-dimensional ultrasound assessment of mesh volumes would have been beneficial, although not essential, in the context of defining the clinical implication of a biomechanical

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phenomenon that has been well documented in previous work.

Vaginal mesh contraction is a serious complication after pelvic organ prolapse repair using armed polypropylene mesh. It is characterized by severe vaginal pain and dyspareunia and on vaginal examination focal tenderness over contracted portions of the mesh. Surgical intervention is often required to alleviate symptoms. It involves mobilization of the mesh, division of the fixation arms, and excision of contracted mesh. Removal of the mesh en-block is reserved, as a last resort, for the most severe and persistent cases. Longer follow-up is required to estimate the outcome after the surgical management, and profound research and development effort is urgently needed for newer graft materials with diminished shrinkage properties.

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MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Product Name: C4001 POLYPROPYLENE HOMOPOLYMER

Manufacturer Information:

Sunoco, Inc. (R&M)
Ten Penn Center
1801 Market Street
Philadelphia, Pennsylvania, 19103-1699

Product Use:

Blow molding,
Extrusion,
Profiles,

Emergency Phone Numbers:

Chemtrec	(800) 424-9300
Sunoco Inc.	(800) 964-8861

Information:

Product Safety Information	(610) 859-1120

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No.	Amount (Vol%)
1-PROPENE, HOMOPOLYMER, ISOTACT	25085-53-4	100 - 100

EXPOSURE GUIDELINES (SEE SECTION 15 FOR ADDITIONAL EXPOSURE LIMITS)

CAS No.	Governing Body	Exposure Limits

3. HAZARDS IDENTIFICATION

- **EMERGENCY OVERVIEW**
  Caution! Low hazard for usual industrial or commercial handling. May cause respiratory tract irritation.

  Hazards Ratings:
  Key: 0 = least, 1 = slight, 2 = moderate, 3 = high, 4 = extreme

	Health	Fire	Reactivity	PPI
NFPA	1	1	0	
HMIS	0	1	0	X

- **POTENTIAL HEALTH EFFECTS**

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- PRE-EXISTING MEDICAL CONDITIONS
  The following diseases or disorders may be aggravated by exposure to this product: Respiratory system; Skin;
- INHALATION
  At elevated temperatures may cause irritation to eyes and respiratory tract.

  LC50 (mg/l): no data
  LC50 (mg/m3): no data
  LC50 (ppm): no data

- SKIN
  Contact with heated product may cause thermal burns.

  Draize Skin Score: no data other
  LD50 (mg/kg): no data

- EYES
  Contact with product at elevated temperatures can result in thermal burns. Slightly irritating but does not injure eye tissue.
- INGESTION
  No effects expected if product is ingested.
  LD50 (g/kg): no data

4. FIRST AID MEASURES

- INHALATION
  Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and continue to monitor. Get medical attention.
- SKIN
  For hot product, immediately immerse in or flush the affected area with large amounts of cold water to dissipate heat. Cover with clean cotton sheeting or gauze and get prompt medical attention. No attempt should be made to remove material from skin or to remove contaminated clothing as the damaged flesh can be easily torn.
- EYES
  For contact with molten product, flush immediately with plenty of cool water for at least 15 minutes. Get medical attention.
- INGESTION
  First aid not normally required.

5. FIRE FIGHTING MEASURES

- EXTINGUISHING MEDIA
  The following media may be used to extinguish a fire involving this material: Water spray; Carbon dioxide; Dry chemical;
- FIRE FIGHTING INSTRUCTIONS
  The use of fresh air equipment such as Self Contained Breathing Apparatus (SCBA) or Supplied Air Respirators should be worn for fire fighting if exposure or potential exposure to products of combustion is expected. Wear structural fire fighting gear.

FLAMMABLE PROPERTIES

	Typical	Minimum	Maximum	Text Result	Units	Method
Flash Point				no data	F	N/A
Autoignition Temperature				no data	F	N/A
Lower Explosion Limit				no data	%	N/A
Upper Explosion Limit				no data	%	N/A

6. ACCIDENTAL RELEASE MEASURES

Vacuum or sweep up material and place in a disposal container. Forms smooth, slippery surfaces on floors, posing an accident risk. Clean up spills immediately, observing precautions in Protective Equipment section.

7. HANDLING AND STORAGE

- **HANDLING**
  Avoid breathing vapors from heated material. Follow all MSDS/label precautions even after container is emptied because it may retain product residue.
- **STORAGE**
  Store in a cool dry place.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Consult With a Health and Safety Professional for Specific Selections

- **ENGINEERING CONTROLS**
  Local exhaust ventilation may be necessary to control any air contaminants to within their TLVs during the use of this product. General dilution ventilation may assist with the reduction of air contaminant concentrations.
- **PERSONAL PROTECTION**
  - **EYE PROTECTION**
    Splash proof chemical goggles are recommended to protect against the splash of product. Full-face shield is recommended to protect against splash of hot product.
  - **GLOVES or HAND PROTECTION**
    Wear insulated impervious protective gear to protect against the splash of hot product.
  - **RESPIRATORY PROTECTION**
    Half-mask air purifying respirator with combination organic vapor and HEPA filter cartridges is acceptable for exposures to ten (10) times the exposure limit. Full-face air purifying respirator with combination organic vapor and HEPA filter cartridges is acceptable for exposures to fifty (50) times the exposure limit.
  - **OTHER**
    Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Property	Typical	Units	Text Result	Reference
Appearance		other	White pellets	
Boiling Point		F	no data	
Bulk Density		lb/gal	no data	
Melting Point		F	160 - 170 deg C	
Molecular Weight		other	no data	
Octanol/Water Coefficient		other	no data	
pH		other	no data	
Specific Gravity		other	0.90 - 0.91	
Solubility In Water		wt %	Negligible	
Odor		other	Odorless	
Odor Threshold		other	no data	
Vapor Pressure		psia	Negligible	
Viscosity (F)		other	no data	
Viscosity (C)		other	no data	

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% Volatile		wt %	no data	

10. STABILITY AND REACTIVITY

- STABILITY
  Stable
- CONDITIONS TO AVOID
  none known
- INCOMPATIBILITY
  The following materials are incompatible with this product: Strong oxidizers such as chlorine, peroxides, chromates, nitric acid, perchlorates, concentrated oxygen, sodium hypochlorite, calcium hypochlorite and permanganates. Chlorine; Nitric acid;
- HAZARDOUS DECOMPOSITION PRODUCTS
  Combustion may produce carbon monoxide, carbon dioxide and other asphyxiants.
- HAZARDOUS POLYMERIZATION
  Will not occur

11. ECOLOGICAL INFORMATION

No data available

12. DISPOSAL CONSIDERATIONS

Follow federal, state and local regulations. Contract to authorized disposal service.

13. TRANSPORT INFORMATION

Governing Body	Mode	Proper Shipping Name
DOT	Ground	Not Regulated

Governing Body	Mode	Hazard Class	UN/NA No.	Label
DOT	Ground	N/A	N/A	

14. REGULATORY INFORMATION

Regulatory List	Component	CAS No.
Inventory - Australia (AICS)	1-PROPENE, HOMOPOLYMER, ISOTACT	25085-53-4
Inventory - Canada - Domestic Substances List	1-PROPENE, HOMOPOLYMER, ISOTACT	25085-53-4
Inventory - China	1-PROPENE, HOMOPOLYMER, ISOTACT	25085-53-4
Inventory - Japan - (ENCS)	1-PROPENE, HOMOPOLYMER, ISOTACT	25085-53-4
Inventory - Korea - Existing and Evaluated	1-PROPENE, HOMOPOLYMER, ISOTACT	25085-53-4
Inventory - Philippines Inventory (PICCS)	1-PROPENE, HOMOPOLYMER, ISOTACT	25085-53-4
Inventory - TSCA - Sect. 8(b) Inventory	1-PROPENE, HOMOPOLYMER, ISOTACT	25085-53-4

Title III Classifications Sections 311,312:

- Acute: NO
- Chronic: NO
- Fire: NO
- Reactivity: NO
- Sudden Release of Pressure: NO

15. OTHER INFORMATION

Follow all MSDS/label precautions even after container is emptied because it may retain product residue. COMPONENT TOXICITY: Polypropylene has been tested in laboratory rats by subcutaneous implantation of discs or powder. Local sarcomas were induced at the site of implantation. No epidemiological studies or case reports suggest any serious chronic health hazards from long-term exposure to polypropylene decomposition products below the irritation level (OARC, 19, 128).

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Expert Report of Dr. Daniel S. Elliot
List of Materials Reviewed

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Original Article

Long-Term (10–15 years) Follow-up after Burch Colposuspension for Urinary Stress Incontinence

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EXHIBIT # 6
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Abstract: The study group comprised 127 patients who underwent a Burch colposuspension for urinary incontinence. All had undergone urodynamic investigation both pre- and postoperatively. All patients had a mean follow-up of 12.4 years (range 10–15); 109 patients had an additional urodynamic investigation at least 10 years after the operation. Following surgery there was an improvement in symptoms of frequency ($P<0.001$), urgency ($P<0.01$) and urge incontinence ($P<0.001$). The cure rate was 93.7%. The only significant changes found on urodynamics were the measurements of the pressure transmission ratio, which were higher postoperatively ($P<0.001$) and remained so after 10 years. The most frequent postoperative complications were de novo detrusor instability (16.6%) and anatomical defects (18.7%). All failed cases were found during the first postoperative year. De novo detrusor instability appeared in 12/17 patients during the first year of follow-up. Postoperative anatomical defects were found only in 4/24 patients after 5 years. Ten years postoperatively most of the anatomical defects had been detected (20/24), stressing the need for long-term follow-up.

Keywords: Burch colposuspension; Complications; Cure rate; Long-term follow-up

Introduction

There are numerous papers concerning different techniques for the surgical treatment of female stress incontinence. Among the suprapubic procedures the Burch colposuspension is one of the most popular, as it seems to give the best results. Nevertheless, the continence rate following Burch colposuspension varies between 67% and over 95% [1–4]. This wide range depends on the criterion for defining cure, the lack of objective evaluation, patient selection and the length of follow-up.

The purpose of this study was to evaluate the long-term clinical, urodynamic data and associated complications following Burch colposuspension for urinary stress incontinence.

Materials and Methods

During 1982–1987 156 consecutive patients underwent a Burch colposuspension procedure for urinary stress incontinence. Postoperative clinical assessment was performed at 3, 6 and 12 months, and once a year thereafter. Urodynamic investigation was performed 6–12 months postoperatively and during 1996.

Of the 156 patients, 29 were omitted for not completing the 10-year follow-up (8 patients died from unrelated causes and 21 patients could not be located). The study group comprised 127 patients, of whom 109 agreed to urodynamic investigation during 1996. The mean duration of follow-up was 12.4 years (range 10–15 years).

Preoperatively, all subjects had a full history taken and underwent gynecologic, urologic and neurologic system examination. Patients were examined with a full bladder for the visual appearance of urinary incontinence. The urodynamic investigation included twin-channel substracted cystometry, uroflowmetry and urethral pressure profile measurements. Cystometry and uroflowmetry were performed using the Urinary

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Investigation System 5000 (Lectromed, Jersey, UK). Measurements were made with the patient in the supine and standing positions using saline solution as the filling substance, at room temperature and at an infusion rate of 100 ml/min. Urethral profile pressures were performed using the 7F Gaeltec dual microtransducer catheter (Gaeltec, Glasgow, Scotland). The bladder was filled with 300 ml saline in the supine position. These tests at rest and at stress in the supine position have been described elsewhere [5]. From the stress profiles we calculated pressure transmission ratios at four equidistant points along the functional urethral length. The operative procedure for correcting urinary stress incontinence was a modified Burch colposuspension [6], using two to three pairs of no. 1 absorbable sutures. The most caudal pair was inserted at the level of the bladder neck, and the other two pairs were inserted more cephalad alongside the bladder base. Of the entire group, 48 patients had a Burch colposuspension only and 79 had a concomitant abdominal hysterectomy for gynecologic indications. Cure was defined as subjective and objective dryness. The methods, definitions and units conform to the standards proposed by the International Continence Society [7]. The statistical method used was McNemar's paired χ^2 test.

Table 1. Patients' characteristics (n = 127)

Age	49.2±5.1	(29–79)
Parity	3.1±1.8	(1–10)
Duration of symptoms (years)	4.7±2.7	(1–17)
Premenopausal	56	(44.0%)
Postmenopausal	71	(56.0%)
*Previous incontinence surgery	23	(18.1%)
Genuine stress incontinence	102	(80.3%)
Mixed stress incontinence	25	(19.7%)

* Vag. Hysterectomy and Ant. Repair = 14. Ant. Repair/Kelly's suture = 5. MM-3 Stamey = 1.

Table 2. Pre- and postoperative clinical data (n = 127)

	Pre-Op		Postop.				
			(1 year)		1996		
	n	%	n	%	$P<$	n	%
Frequency							
Diurnal	66	51.9	31	24.4	0.001	33	25.9
Nocturnal	54	42.5	22	17.3	0.001	25	19.6
Urgency	71	55.9	32	25.2	0.01	37	29.1
Urge incontinence	42	33.0	12	9.4	0.001	13	10.2
Stress incontinence	127	100	*8	6.3	0.001	2	

* Six patients were reoperated.

Results

One hundred and twenty-seven patients completed at least the 10-year follow-up. Table 1 describes the patient characteristics. The mean age was 49.2 years; 23 patients (18.1%) had had previous anti-incontinence surgery; 58 (45.6%) had undergone Burch colposuspension only; the other 69 (54.4%) had had adjuvant surgery, mainly abdominal hysterectomy. Following surgery, as detected from a restrospective chart review, there was an immediate significant relief in the symptoms of frequency (P<0.001), urgency (P<0.01), urge incontinence (P<0.001) and stress incontinence (P<0.001) which remain throughout the years of follow-up (Table 2). The failure rate was 6.3%. All failed cases were found within the first postoperative year and 6 of those patients were reoperated. There were no changes in the cystometric and uroflowmetry parameters in the immediate and long-term measurements (Table 3). On urethral pressure profile measurements (Table 4) the pressure transmission ratio was found to be significantly higher after 1 year (P<0.001) and still significantly higher at the measurements during 1996 (P<0.005).

The most frequent postoperative complications were detrusor instability in 29 patients (22.2%) and anatomical defects in 24 patients (18.7%). Other complications, as listed in Table 5 appeared much less frequently. Concerning the appearance of detrusor instability, we divided the patient group into those with preoperative stable bladder (102 patients) and those with preoperative mixed incontinence (25 patients). Postoperatively the preoperative stable bladder group developed de novo detrusor instability in 17 cases (16.6%), whereas in the mixed incontinence group 13 out of 25 patients (52%) had stable bladders on cystometry postoperatively. Table 6 summarizes the time of diagnosed postoperative complications. Recurrent urinary stress incontinence was found in 8 patients, all of them in the first 12 months of follow-up. Six patients were successfully

Table 3. Urodynamic data (n = 109)

	Preop	Postop 1 yr	Postop 1996
Capacity (ml)	486.2±58.7	474.3±49.8	459.5±52.3
Residual volume (ml)	19.4±24.6	22.9±34.2	24.6±32.8
Pressure rise on filling (CmH_2O)	12.9±7.1	13.6±8.3	13.9±7.9
Pressure rise on standing (cmH_2O)	9.3±7.8	10.8±7.4	11.8±7.5
Maximal voiding pressure (CmH_2O)	36.8±10.4	35.2±11.6	33.8±10.7
Peak flow rate (ml/s)	27.6±7.4	25.9±7.3	24.3±7.6

P = NS for each value.

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Table 4. Urethral pressure profile (n = 109)

	Preop	Postop (1 yr)	$P<$	Postop (1996)	$P<$
At rest					
Absolute length (mm)	46.8±7.0	47.1±9.3	NS	46.2±9.6	
Functional length (mm)	38.2±4.9	39.9±7.4	NS	37.1±8.3	
Maximal urethral pressure (CmH_2O)	53.2±16.1	54.7±14.9	NS	46.8±15.4	NS
Maximal urethral closure pressure (CmH_2O)	46.9±15.3	45.8±13.9	NS	43.1±14.7	
Pressure transmission ratio (%)					
Q_1	84.6±11.2	106.7±12.3	0.001	100.3±11.6	0.005
Q_2	86.3±9.4	107.9±14.0	0.001	102.5±15.4	0.005
Q_3	74.7±16.3	97.3±16.8	0.005	82.4±17.3	NS
Q_4	65.1±15.8	81.4±19.3	0.05	70.1±16.7	NS

Table 5. Postoperative complications (n = 127)

Detrusor instability	29 (22.2%)
Rectoenterocele	18 (14.1%)
Vault prolapse	4 (3.1%)
Uterine prolapse	2 (1.5%)
Vesicovaginal fistula	1 (0.8%)
Dyspareunia	5 (3.9%)
Recurrent USI	8 (6.2%)
Late voiding difficulties (residual volume more than 100 ml)	5 (3.9%)
Recurrent UTI (more than 3 episodes/year)	6 (4.7%)

reoperated. De novo detrusor instability was found in 17 patients, the majority of them (12 patients) being diagnosed during the first postoperative cystometry. The same applies to the disappearance of detrusor instability in the preoperative mixed incontinence group, where 10/25 patients were found to have a stable bladder during their first postoperative cystometry. Postoperative anatomical defects were found in 24 patients. In the first 2 postoperative years only 4 patients were found with anatomical defects. After 5 years less than half (11/24) were found to have anatomical defects. Ten years postoperatively most of the anatomical defects (20/24) had been found. We tried to detect risk factors for failed surgery, and found that pre- and postoperative detrusor instability, previous incontinence surgery, advanced age and menopausal status appear more frequently in the failed group. The differences did not reach statistical significance, probably because of the small number of failed cases.

Discussion

The importance of long-term follow-up after Burch colposuspension has already been advocated [6]. Nevertheless, although this is probably the most popular surgical procedure for urinary incontinence ony a few studies have reported on its long-term effectiveness on the basis of subjective and objective pre- and postoperative assessment by urodynamic measurements. Some studies suggested that the cure rate declines over the years, from 92% after 1 year to 69% after 10 years [4]. A less pronounced decline was found by others [8], form 97.3% after 1 year to 90.3% after 10 years. Our results disagree with these findings, as after the first postoperative year found no further failures. These findings are in accord with other publications [9], which found a constant continent rate from the second to the 10th postoperative years.

Our long-term urethral pressure profile measurements reveal that there are no changes in urethral length and urethral closure pressure between the pre- and postoperative measurements. These results confirm the findings of the short postoperative follow-up [10], in contrast to others [3], who found a significant increase in urethral functional length and urethral closure pressures. The only significant changes found on urethral pressure profile measurements in this study were higher transmission ratios found postoperatively in both the short and the long-term measurements. Only a single paper [3] was found that measured pressure transmission ratios in the long-term follow-up, supporting our findings.

Table 6. Time of diagnosed postoperative complications

	1 yr	2 yrs	5 yrs	10 yrs	15 yrs
Recurrent stress incontinence	*8	2	2	2	2
De novo DI (preoperative stable bladder 102 patients)	12	14	16	16	17
DI (preoperative mixed incontinence 25 patients)	10	10	10	11	12
Rectoenterocele (18) Vault prolapse (4) Uterine prolapse (2) — 24 patients	2	4	11	20	24

* Six patients were reoperated.

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The major postoperative complications found in our series were detrusor instability (22.2%) and anatomical defects (18.7%) Detrusor instability is a well recognized complication following Burch colposuspension. In dealing with this complication one should separate those patients with preoperative mixed incontinence from those with a preoperative stable bladder who develop de novo detrusor instability postoperatively. This latter group has been reviewed in the literature [11]. Six studies were reviewed, with a total of 396 patients, 17% of whom devleoped de novo detrusor instability. The prevalence varied from 5% to 27%. These figures were confirmed in a more recent work [4], as in the present series (16.6%). Our results indicate that 14/17 patients developed (de novo) detrusor instability in the short postoperative period, and only few others developed de novo instability over the years. On the other hand, patients with preoperative mixed incontinence in the present series were cured from detrusor instability following surgery in 50% of cases, as previously reported by us [12] and reviewed by others [11]. In a review of five papers the authors found a 55% cure rate for detrusor instability following Burch colposuspension (range 66%–15%). To date no satisfactory explanation as to why patients with preoperative detrusor instability are cured of their detrusor instability following Burch colposuspension can be provided, maybe because in the majority of cases detrusor instability is still idiopathic in origin.

Anatomical defects following Burch colposuspension were found in 18.7% of our patients. We included rectoenterocele (14.1%), vault prolapse (3.1%) and uterine prolapse (1.5%), all of which were severe enough to require surgical repair. These figures confirm other publications finding anatomical defects ranging from 7.6% to 26.7% [1,2,4]. The most acceptable explanation for this complication is the rotation of the vaginal axis anteriorly, allowing intra-abdominal pressure to be transmitted through the posterior cul de sac. Another possibility is that candidates for colposuspension have predisposing relaxation of the pelvic floor, with a greater tendency to develop anatomical defects. Our opinion is that both these theories combine, as patients with marked pelvic relaxation are candidates for Burch colposuspension, whereas those without marked pelvic relaxation tend to undergo minor procedures, such as needle suspension or vaginal slings. Postoperative anatomical defects are not recognized as a major complication following these minor procedures. The different rates of anatomical defects following Burch colposuspension may be explained by the various techniques with which this operation is performed, patient selection, the inclusion or not of rectocele as an anatomical defect following surgery, and the duration of follow-up. Our results indicate that long-term follow-up has been proved essential in tracing cases of anatomical defects, as more than 50% of our cases were detected after 5 years of follow-up, stressing the importance of long-term follow-up after Burch colposuspension.

Risk factors for failed surgery have been previously identified in the literature [2–4]: they include previous incontinence surgery, detrusor instability and advanced age. Our results, although not reaching statistical difference, tend to confirm these factors as imposing an increased risk of failure following Burch colposuspension.

In summary, our long-term cure rate with Burch colposuspension was found to be comparable with that reported by others. This was expressed objectively by the high pressure transmission ratios fond on urethral pressure profile measurements 10–15 years after surgery. All our failures occurred within the first postoperative year. The most significant complications are de novo detrusor instability (16.6%) and anatomical defects (18.9%), half of which appeared only 5 years postoperatively, stressing the need for long-term follow-up.

References

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10 yr

14 yr

EDITORIAL COMMENT: As the results of this study indicate, there remains little doubt that in the hands of expert surgeons the Burch colposuspension is a durable and effective operation for uncomplicated stress urinary incontinence. Even if one considers the most pessimistic possible results of this study, i.e. that all of the patients lost to follow-up and who did not have follow-up urodynamic